The Nancy Nail[™]

SURGICAL TECHNIQUE

For Elastic Stable Intramedullary Nailing (ESIN)



1





Nancy Nail Instruments:

- T-handle Chuck for insertion
- Pin Cutter for cutting nail to appropriate length
- Needle Nose Pliers for removal

T-Handle Chuck

Pin Cutter

Need	le N	lose	Pliers

Cat. No.	Implants-Nail and Endcap Kits
8006-10-100	Nail, Nancy, 1.0 mm, Sterile
8006-20-450	Nail & Endcap, Kit, Nancy, 2.0 mm, Sterile
8006-25-450	Nail & Endcap, Kit, Nancy, 2.5 mm, Sterile
8006-30-450	Nail & Endcap, Kit, Nancy, 3.0 mm, Sterile
8006-35-450	Nail & Endcap, Kit, Nancy, 3.5 mm, Sterile
8006-40-450	Nail & Endcap, Kit, Nancy, 4.0 mm, Sterile

Cat. No.	Instrumentation	
8206-01-000	T-handle Chuck	
8206-02-000	Needle Nose Pliers	
8206-03-000	Pin Cutter, Nancy Nail	
8206-04-000	Diameter Gauge	
8206-05-000	Slap Hammer for Pliers	
13550-120	2.9 mm Drill Bit	
13560-120	3.5 mm Drill Bit	
14545	3.8 mm Drill Bit	
13564-120	4.0 mm Drill Bit	
14625	4.8 mm Drill Bit	
8299-30-000	Case, Instrument, Nancy Nail	

Nancy Nails are manufactured from TiMAX[™], a titanium alloy with proprietary surface treatment which provides increased fatigue resistance. They can be used to treat femoral and tibial fractures in children and adolescents, and humeral, radial, and ulnar fractures in both pediatric and adult patients. A 1.0mm diameter, 100mm length Nancy Nail is also available to treat metacarpal and metatarsal fractures. Contact DePuy at (800) 366-8143 or your local DePuy sales representative for sales information or further information on other applications for the Nancy Nail.

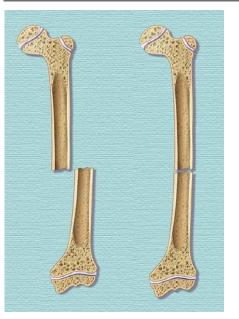


The Nancy Nail is specifically designed for Elastic Stable Intramedullary Nailing (ESIN) fracture fixation. Indications include:

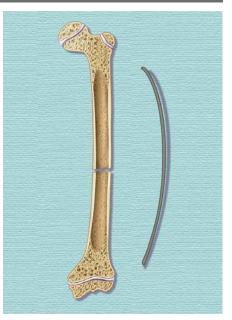
- Pediatric (4-14 yrs., <140 lbs.) Upper & Lower Extremity Long Bone Fractures
- Adult Upper Extremity Long Bone Fractures
- Metacarpal, Metatarsal and Phalangeal Fractures (Ø1mm)

The Nancy Nail[™]

Surgical Technique for Pediatric Femur Fractures

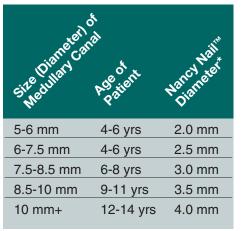


1. Reduce the fracture. Final reduction should be aided by an image intensifier.



2. Choose a nail of appropriate diameter, depending upon the patient's age and medullary canal size (see Table 1). Bend the nail in the same direction as the spatula tip's curvature. The apex of the curve, after bending, must be at the level of the fracture.

Table 1* (See Step #2) Choosing Nail Diameter*

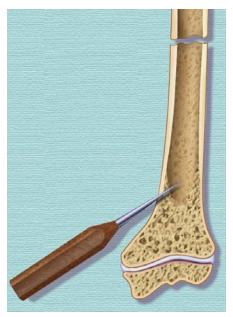


Note: The Nancy Nail is not intended for use in children under 4 yrs. of age or in patients over 140 lbs. (65 kg)

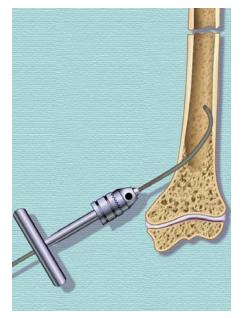
*Nail diameter selection depends on both age and medullary canal diameter.

ADVANTAGES OF NANCY NAIL ESIN:

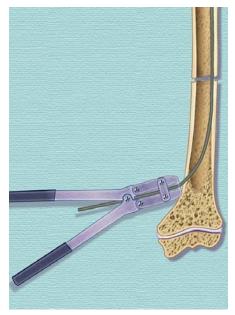
- Eliminates Casting
- Allows Earlier Weight Bearing
- Minimal Skin Incision
- Easy Implantation
- Minimal Growth
 Disturbance
- Reduced Hospital Care



3. Make the incision at the metaphyseal cortex, taking care to avoid the growth plate. Using a square awl or a drill bit, drill a hole at an oblique angle approximately 1cm above the growth plate.



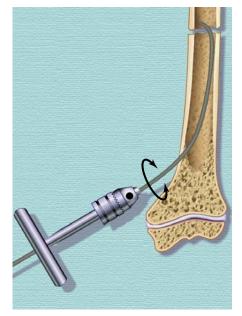
4. Using the T-handle Chuck, introduce the nail into the bone. Push the nail into the medullary canal as far as the fracture site. Re-orient the nail at the fracture site, if necessary, and push the nail into the second bone fragment. Use of an image intensifier is required.



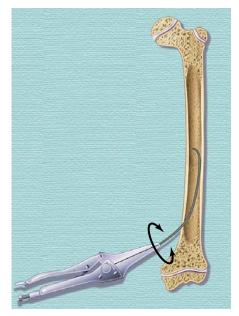
7. Bend the exposed portion of the Nancy Nail until it is perpendicular to the femur. Using the Pin Cutter, cut the exposed nail near the surface of the bone. To facilitate removal of the nail, allow 5mm-8mm to remain outside the cortex. Place the appropriate Endcap on the exposed nail tip.



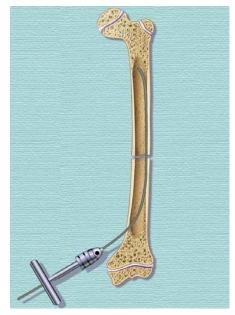
8. A minimum of two nails is required to stabilize the fracture. Repeat the same procedure to insert a second nail through the opposite cortex such that the curve is opposite the position of the first nail. The apex of the curve, after bending, must be at the level of the fracture. Check reduction alignment using an image intensifier.



5. Push the nail past the fracture site and continue advancing the nail proximally. If an angular deformity is present after the nail is inserted, the deformity can be corrected and minimized by rotating the nail. Verify correct anatomic position using an image intensifier.



9. Once the fracture has healed as determined by the surgeon, remove the Endcap and extract the Nancy Nails using the Needle Nose Pliers.



6. Impact the proximal end of the nail into the cancellous bone of the opposite metaphysis. In some instances, advancing each nail in small increments across the fracture site, alternating between the medial and lateral nails, will provide improved reduction.

Important:

This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications:

The use of metallic surgical appliances (screws, plates, intramedullary nails, compression hip screws, pins and wires) provides the orthopaedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide 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 subjected to repeated stress in use, which can result in metal fatigue.

Contraindications:

Screws, plates, intramedullary nails, compression hip screws, pins and wires are contraindicated in: active infection, conditions which tend to retard healing such as blood supply limitations, previous infections, insufficient quantity or quality of bone to permit stabilization of the facture complex, conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process, foreign body sensitivity, and cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients.

Additional Contraindication for Retrograde Femoral Nailing:

A history of septic arthritis of the knee and knee extension contracture with inability to attain at least 45° of flexion.

Additional Contraindications for Compression Hip Screws only:

Inadequate implant support due to the lack of medial buttress.

Warnings and Precautions:

Bone screws and pins are intended for partial weight bearing and non-weight bearing applications. These components cannot be expected to withstand the unsupported stresses of full weight bearing.

Adverse Events:

The following are the most frequent adverse events after fixation with orthopaedic screws, plates, intramedullary nails, compression hip screws, pins and wires: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation; infection and adverse reactions to the device material.

Additional Adverse Events for Compression Hip Screw only:

Screw cutout of the femoral head (usually associated with osteoporotic bone).

For more information about DePuy products, visit our web site at www.jnjgateway.com.



DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581-0988 USA Tel: +1 (800) 366 8143 Fax: +1 (574) 371 4865 **DePuy International Ltd** St Anthony's Road Leeds LS11 8DT England Tel: +44 (113) 387 7800 Fax: +44 (113) 387 7890