THE ForeSIGHT® Nail SYSTEM

Surgical Technique
Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.
INDICATIONS
The ForeSight Nail is indicated for shaft fractures of the ulna and/or radius. It can be used in closed or open fractures and can be used with segmental, comminuted fractures, in osteoporotic bone, multiply injured patients, and in patients with poor skin conditions (Figure 1).

OVERVIEW
The ForeSight Nail is designed to restore anatomic bow of radius and gentle S-shaped curve of ulna. Straight nails are bent at time of surgery to provide a custom fit. Static proximal and distal interlocking is possible to achieve rotational stability at fracture site and to maintain bone length.

Nailing of ulna is accomplished through a portal made in proximal olecranon. Entry portal for nailing of radius is made on radial side of Lister’s tubercle beneath extensor carpi radialis brevis tendon. In both bone fractures, ulna is reduced,reamed if necessary, and temporarily stabilized to maintain reduction. Ulna is then nailed antegrade first, providing a more stable forearm for retrograde nailing of radius. In segmental fractures, middle fragment should be stabilized prior to reaming and nailing to maintain control of fragment and prevent periosteal stripping.

KEY BENEFITS
• Closed technique provides benefit in reduced surgical exposure, decreased periosteal stripping of fracture site, and lessens cosmetic concerns.
• In both bone fractures where one bone requires open reduction, other bone can be nailed using a closed technique.
• Static interlocking provides rotational control.
• Useful in treating multiply injured patients and patients with poor skin conditions.
NAIL AND ANATOMIC CURVE DETERMINATION

X-rays are required to select correct nail length and diameter. In small forearms, medullary canal may not be of sufficient size to use intramedullary fixation of this type. Two malleable templates are provided to determine nail length and canal contour using A-P X-ray of uninjured forearm. If both forearms are injured, an X-ray of any normal adult forearm can be used as a guide for contouring nails. Make this X-ray with tube 40 inches from forearm to eliminate magnification. Bend templates to match contours of radius and ulna using an X-ray (Figure 2) and then sterilize contoured templates for use in sterile field. Insert selected nail in nail bender so that proximal screw hole is not visible from above. Make several small bends along length of nail in order to create a smooth curve according to the sterile contoured template (Figure 3). Take care to not make sharp bends in nail as this will cause a kink in the implant.

PATIENT POSITIONING AND FRACTURE REDUCTION

Place patient supine on operating table equipped with radiolucent hand table (Figures 4 & 5). Reduction can be achieved in forearm fractures either in a closed or open manner. If closed reduction can be achieved, a traction device or surgical assistant may be required to maintain adequate distraction of fragments. If open reduction is necessary, expose ulnar fractures through routine subcutaneous approach. Exposure for open reduction should be limited to reduce periosteal stripping at fracture site if possible. Expose fracture in distal half of radius through anterior Henry approach. For fractures in proximal half of radius, use posterior Thompson approach. Great care should be exercised to avoid posterior interosseous branch of radial nerve. Material from reamers is
usually sufficient for local bone grafting. Large butterfly fragments should be wired into place.

**SURGICAL APPROACH**

Approach to ulna entry portal is to make longitudinal incision approximately 1 cm long at tip of olecranon. Dissect through subcutaneous tissues and triceps fascia. Avoid dissection medial to olecranon in region of ulnar nerve.

Approach to radius entry portal is to make 2.5 to 3 cm longitudinal incision over distal radius on radial side of Lister’s tubercle. Bluntly dissect subcutaneous tissues to avoid injury to branches of superficial radial nerve. Identify and incise longitudinally extensor retinaculum, leaving proximal third intact. Retract extensor carpi radialis brevis tendon to radial side.

**CANAL PREPARATION**

Ulna should be reduced first in both bone fractures. Entry point into ulna should be in line with center of olecranon process and center of medullary canal. Insert 1.9 mm trocar pin at entry point. Enlarge entry portal with 6.0 mm cannulated reamer over trocar pin and ream first 2 to 2.5 cm to accept larger diameter of nail (Figure 6). Groove on cannulated reamer indicates length of large end of nail. To ease nail insertion, reaming of canal may be necessary. Before reaming, it is important to stabilize middle fragment of segmental fractures to prevent soft tissue stripping of fragment during reaming. This is achieved with a small incision and a small bone holding forceps. Manual reamers 3.0-5.0 (0.5 mm increments) and 6.0 mm may be used to enlarge canal 0.5 to 1.0 mm over selected nail diameter (Figure 7). After last reamer is used, replace it with 2.4 mm straight guide rod. After ulnar reduction and temporary stabilization, reduce radial fracture. Entry into radius should be at distal radius on radial side of Lister’s tubercle beneath the extensor carpi.
radialis brevis tendon, 5 mm from articular surface. Repeat trocar pin entry at a 30° angle and reaming with 6.0 mm cannulated reamer (Figure 8). Use manual reamers to enlarge radial canal if necessary (Figure 9). When reaming radial canal, it may be necessary to bend tip of 3.0 mm reamer to allow entry into canal without reaming through volar cortex. Leave last reamer in place or insert 2.4 mm guide rod to maintain reduction of radius while fixing ulna.

**DRILL GUIDE ASSEMBLY AND NAIL INSERTION**

Proper nail contouring prior to insertion and orientation of contoured implants with respect to anatomy are crucial. To assemble guide, insert bolt through drill guide and completely thread into nail. Thread driver/extractor into bolt and tighten entire assembly with 9/16” wrench (Figure 10). Remove guide rod and drive nail past fracture site until fully seated under hand pressure or by lightly tapping with slotted hammer (Figure 11).

**INTERLOCKING SCREW INSERTION**

The ForeSight Nail is interlocked with two screw types. At driving end, it is locked with a fully threaded 2.7 mm self-tapping screw. At non-driving end it is locked with 2.7 mm unicortical screws. There is one driving end screw hole and two nondriving end screw holes 90° to each other. Decision of whether to lock statically should be made based on fracture stability and expected patient compliance. Main advantages of static locking is rotational control and length maintenance. There are also flutes at nondriving end of nail which will provide additional rotational control. Locking screws are placed radial to ulnar in ulna and radial to ulnar in radius.
To interlock driving end of nail, insert 1.9 mm fuchsia drill sleeve into 8 mm teal screw sleeve, and place both sleeves in the hole in drill guide. Make stab incision through skin using sleeves for position and spread soft tissues by blunt dissection until cortex is exposed. Place both sleeves against cortex. Drill 1.9 mm trocar pin across both cortices. Measure for screw length using screw length gauge against fuchsia drill sleeve for accurate reading (Figure 12). Remove trocar pin and 1.9 mm fuchsia drill sleeve. Assemble correct length 2.7 mm self-tapping fully threaded screw onto hex shaft by clamping screw holder onto head of screw. Insert screw and screw holder into screw sleeve, and carefully drive through bone using hex shaft and quick release teardrop handle (Figure 13). Simultaneously, push hexdriver while pulling teal screw sleeve to release holder from head of screw.

To interlock nondriving end of nail, use image intensifier to find perfect circle view of screw hole. Make incision through skin over hole and expose bone while taking care to avoid injury to posterior interosseous nerve when proximally locking radial nail. Insert radiolucent amber drill sleeve into drill sleeve with handle and place assembly in wound and against bone (Figure 14). While holding sleeve assembly parallel to image intensifier beam, drill 1.9 mm trocar pin across both cortices and through hole of nail. Care and a steady hand are necessary to drill trocar pin through the locking hole. Measure for screw length using screw length gauge against amber drill sleeve for accurate reading. Remove trocar and amber drill sleeve and place correct length 2.7 mm unicortical screw with screw holder into sleeve and insert using hex shaft and quick release teardrop handle.

Thoroughly review nail and locking screw placement using image intensifier. Remove drill guide bolt with 9/16" wrench and close wound in routine fashion (Figure 15). Locking nail at driving end only will prevent backing out of nail that can occur after fracture healing.
**Bone Grafting**

If closed reduction technique is used, bone grafting is usually unnecessary. If open reduction is necessary, bone graft should be applied to the fracture site. Usually bone saved from entry portal reamer and manual reamers is sufficient, and this material should be saved throughout procedure.

**Postoperative Care**

If secure rigid fixation is achieved, plaster sugar-tong splint is applied and kept in place for two weeks. Thereafter, removable sugar-tong orthosis is worn until bridging callus is present. Orthosis is removed frequently for exercise. If fixation is not secure or patient compliance is questionable, a long arm cast should be applied with forearm in neutral rotation and elbow flexed in 90° of flexion. Cast is worn until fully healed. If nail removal is necessary, it should not be performed until fracture is fully healed and not before one year postop.

Complications should be minimal if technique is followed correctly. Little difficulty should be encountered in nailing ulna. The following complications may occur when nailing radius. Nail may protrude through cortex beyond dorsal curve, or it may split distal fragment. In small forearms medullary canal may not be of sufficient size to use intramedullary fixation of this type. Driving nail through a tight medullary canal may be difficult and it should not be forced.

**Nail Removal**

Attach drill guide bolt to driving end of nail. Thread driver/extractor into bolt and tighten using 9/16” wrench. Make stab wounds over original incisions and remove locking screws with hex shaft attached to quick release teardrop handle. If unable to remove nail with manual force, use slotted hammer on driver/extractor. Close in usual manner.
Intramedullary nails provide an alternative to open reduction and fixation of a variety of fractures. The objective of this closed technique as compared to open techniques is to provide fixation with minimal trauma, reduced risk of infection, and reduced blood loss. As with all orthopaedic devices, success varies with the patient, even in the less difficult case there is a risk of complications. The surgeon is cautioned that any of the circumstances listed under categories below may reduce the chances of a successful outcome.

**BASIC STRUCUTURE**

The Smith & Nephew Intramedullary Nail System consists of interlocking intramedullary nails, interlocking reconstruction nails, intramedullary supracondylar nails, intramedullary hip screw systems, and interlocking intramedullary modular nails. All of these systems listed previously accept locking screws. The locking screws reduce the likelihood of shortening and rotation of femoral shaft fractures. All nails are available in a variety of diameters and lengths. All implantable devices are for single use only.

**Intramedullary interlocking nails** are curved or straight nails that contain holes proximally and distally to accept locking screws.

**Interlocking reconstruction nails** are curved nails that contain holes proximally to accept screws which thread into the femoral head for compression and rotational stability; distally there are two holes to accept locking screws. Interlocking reconstruction nails are available in a variety of diameters and lengths in straight and right models, as proximal screw holes are antverted 8° with respect to the plane containing the curve of the nail.

**Intramedullary supracondylar nails** can contain holes throughout their length or at either end of the nail to accept locking screws.

**Intramedullary hip screw systems** contain a pre-bent nail containing holes proximally and distally to accept a lag screw and locking screws, respectively. Intramedullary hip screws are available in a variety of diameters, lengths, and neck/shaft angles.

The interlocking intramedullary modular nail consists of a proximal component, central component, distal component, and a drill bit. The proximal component is available in both an intramedullary hip screw (IMHS) and interlocking reconstruction (Recon) design. The intramedullary hip screw proximal component accepts a lag screw and the interlocking reconstruction design accepts two locking screws. The distal component also accepts locking screws. The cannulated drill bit is inserted into the nail to provide an aid in nail insertion and extraction.

The ReVision™ Nail consists of an intramedullary nail with holes at each end to accept 5.0 mm locking screws. The locking screws reduce the likelihood of shortening and rotation of the fusion site.

**MATERIALS**

Intramedullary nails, locking screws, sleeves, set screws, and lag screws are manufactured from stainless steel (ASTM F 138 and ISO 8832/1).

**INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS**

**General**

The general principles of patient selection and sound surgical judgment apply to the intramedullary nailing procedure. The size and shape of the long bones present limiting restrictions on the size and strength of implants.

Indications for interlocking intramedullary nails include severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; and bone lengthening/shorenting. Femoral interlocking nails include the indication for proximal, middle and distal third femoral shaft fractures. Tibial interlocking nails also include the same indications for tibial shaft fractures.

**Humeral interlocking intramedullary nails** are indicated for humeral shaft fractures, including severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; proximal, middle and distal third shaft fractures; polytrauma and/or multiple fractures; humerus reconstruction following tumor resection and grafting, and prophylactic nailing of impending pathologic fractures.

**ForeSight forearm interlocking intramedullary nails** are indicated for radial and ulnar shaft fractures, including severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; proximal middle and distal third shaft fractures; polytrauma and/or multiple fractures.

**Interlocking reconstruction nails** are indicated for the tibia following trauma; failed total knee arthroplasty; severe knee arthritis; severe deformity secondary to untreated tibial plateau fractures; severe plim fractures with trauma to the tibial plateau.

**ForeSight interlocking intramedullary nails** are indicated for radial and ulnar shaft fractures, including severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; proximal middle and distal third shaft fractures; polytrauma and/or multiple fractures.

**Interlocking reconstruction nails** are indicated for the tibia following trauma; failed total knee arthroplasty; severe knee arthritis; severe deformity secondary to untreated tibial plateau fractures; severe plim fractures with trauma to the tibial plateau.

**Indications**

1. These systems should not be used in crossing open epiphyseal plates.

2. Insufficient quantity or quality of bone, obliterated medullary canal or conditions which tend to retard healing, also, blood supply limitations, previous infections, etc.

**Contraindications**

1. Excessive comminution, implying that the bone is not in two pieces.

2. Insufficient quantity or quality of bone, obliterated medullary canal or conditions which tend to retard healing, also, blood supply limitations, previous infections, etc.

3. Foreign-body sensitivity, where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.

4. Active infection.

5. Conditions which tend to preemp the patient’s ability or willingness to restrict activities or to follow directions during the healing period.

6. The forearm nail should not be used in children who have not reached skeletal maturity.

In addition to the contraindications listed above, reconstruction nails are also contraindicated for any fracture which can be suitably fixed with a standard interlocking intramedullary nail.

Also in addition to the contraindications listed above, intramedullary hip screw systems are also contraindicated for a severe bow or gross distortion of the femur.

**Possible Adverse Effects**

1. Loosening, bending, cracking, or fracture of the nails or screws, loss of fixation in bone attributable to nonunion, osteoporosis markedly unstable comminuted fractures or one or more of the factors listed in Contraindications above and/or Warnings and Precautions below.

2. Loss of anatomic position with nonunion or malunion with rotation or angulation.

3. Infections, both deep and superficial.

4. Allergies and other reactions to device materials.

5. Irritional injury of soft tissues, including impinge ment syndrome.

6. Supracondylar fractures from retrograde nailing.

**WARRIORS AND PRECAUTIONS**

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

**Preoperative**

1. Use care in handling and storage of implant com ponents. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environ ments such as salt air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instrument compo nents or implants have been damaged storage or prior procedures.

2. Patient conditions and/or predispositions, such as those addressed in Contraindications above, should be avoided.

3. An adequate inventory of implant sizes should be available at the time of surgery.

4. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.

5. Certain special surgical instruments are required to perform this surgery including an image integ rifier and an appropriate fracture table. Review of the use and handling of these instruments is recommended.

6. Before the initial experience, we recommend that the surgeon acquaint himself with the device and attend a technique seminar. Surgical technique brochures are available upon request at no charge, and should be reviewed by the surgeon prior to initial surgery. Skill in the use of this tech nique should be acquired on less complicated
fractures before attempting its use in unstable, difficult fractures. The surgical technique provides reaming information for each nail.

7. The patient should be advised that a second more minor procedure for the removal of implants is usually necessary.

Operative

1. Please refer to the surgical technique for the specific nail for important reaming directions.
2. Selection of the proper nail length and diameter is extremely important and must be carefully sized to the patient.
3. The patient’s age, weight, and cortical bone quantity must be evaluated for the proper implant selection. The most appropriate nail should be selected after reviewing the available sizes. The largest implant that fills the canal should be used.
4. Care should be taken not to scratch, bend sharply, or cut metal components during surgery for the reasons stated in number one of the preoperative section of Warnings and Precautions. Once removed from the patient, implants should never be reused since internal stresses (in the implant) that are not visible may lead to early bending or fracture.
5. A stable construct should be achieved and verified under image intensification.
6. For femoral interlocking intramedullary nails, the trochanteric entrance hole should be in line with the femoral medullary canal in the lateral aspect of the trochanteric fossa and not at the tip of the trochanter. An excessive lateral placement of the entrance hole may result in eccentric reaming and comminution of the medullary cortex of the proximal fragment at the fracture site.
7. For tibial interlocking intramedullary nails, the entrance hole of the tibia should be proximal to the tibia tubercle in the midline behind or slightly medial to the patellar ligament. An excessive distal placement of the entrance hole may result in entering the inner distal cortex at a steep angle and splitting the bone.
8. The use of Smith & Nephew Locking Screws is necessary for strength and compatibility. Please refer to the outer carton labels, surgical technique, or product catalog for information on the correct size of screws for each nail.
9. For retrograde insertion of humeral interlocking intramedullary nails, nails are inserted through a hole 1 cm wide by 2 cm long starting 2-3 cm proximal to the olecranon fossa. The entry portal is in the lateral aspect of the greater tuberosity for antegrade insertion. An incorrect entry portal will increase the chance of breaking the humeral cortex during nail insertion.
10. For interlocking construction nails, the proper sized proximal screws are necessary. Both proximal screws should be used where possible for better fixation of the proximal head.
11. In certain cases a bone graft may be appropriate.
12. For intramedullary hip screw systems, the intramedullary nail uses the Smith & Nephew standard lag screw proximally in conjunction with an intramedullary hip screw sleeve and set screw.
13. For the ReVision nail, the inner diameter of bone must be 1.0–1.5 mm larger than the inserted nail whether reamed or not. Nail diameter “sounds” are available to determine inner bone diameter.

Postoperative

1. Intramedullary nails are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. All patients should be cautioned against significant weight bearing prior to good callus formation. For this reason patients who are obese and/or noncompliant, as well as patients who could be predisposed to delayed or nonunion, must have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries.
2. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the nail’s screw hole, as this situation places greater stress on the nail at the location of the transverse screw hole.
3. Postoperative directions and warnings to patients by physicians, and appropriate nursing care, are extremely important, particularly those admonitions that concern early weight bearing or active use of the extremities. These activities substantially increase the stress on implants that can lead to complications.
4. Supplemental support may be necessary for those patients using external devices for ambulatory assistance.
5. Periodic X-ray examinations for at least the first six (6) months postoperatively are recommended for close comparison with postoperative conditions to detect changes in position, nonunion, loosening, bending, or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and early revision considered.
6. While the surgeon must make the final decision on implant removal, whenever possible and practical for the patient, fixation devices should be removed once their service as an aid to healing is accomplished. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.
7. Even after full healing, the patient should be cautioned that refracture is more likely with the implant in place and soon after its removal, than later, when voids in the bone left by implant removal have been filled in completely.
8. Early partial weight bearing should be considered only in those cases with stable fractures and good bone-to-bone contact and excellent patient cooperation.
9. Patients should be cautioned against unassembled activity that requires walking or lifting.
10. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.

PACKAGING AND LABELING
All implants are provided sterile and should be accepted only if the factory packaging and labeling arrive intact. If the sterile barrier has been broken, refer to the Resterilization section below for additional instructions.

STERILIZATION
Metal components have been sterilized by a minimum of 25 kilo Grays of gamma irradiation. Inspect packaging for punctures or other damage prior to surgery.

RESTERILIZATION
Metal components may be resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all the original packaging and labeling. Protect prosthesis, particularly mating surfaces, from contact with metal or other hard objects. The following process parameters are recommended for these devices: Prevacuum cycle, 4 minutes at 132° C to 135° C, followed by 20 minutes of drying time.

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

INFORMATION
For further information, please contact Customer Service at 1-800-238-7538.
ForeSight Nail Implant Set
Cat. No. 7112-4000
(Implants can be ordered as a set or individually using the following catalog numbers.)

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Locking Screws

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* Packaged in quantities of six, nonsterile.
** Packaged in quantities of six, sterile.

The following statement is required by the U.S. FDA: WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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