Tibia Nail System
Surgical Technique
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Warning
This instruction is for reference only.
Operation must be performed under the guides of professional doctors.
Tibia Nail System

Introduction
Intramedullary nailing has become increasingly popular as a treatment for long bone fractures, and it is suitable for all fractures extending from 7-8 cm distal to the tibial plateau, to within 5.5 cm of the distal articular surface, provided that the epiphyses are closed. The Intramedullary Fixation System is a set of intramedullary nails which offers several advantages over existing systems. A major advantage of the system is the ability to insert both proximal and distal locking screws accurately and quickly without the use of X-rays, using an external mechanical targeting device. The locking screw has a smooth shank 4 mm in diameter which penetrates the distal cortex. A locking screw of this configuration is much stronger for a given diameter than a fully threaded screw. The locking holes in the nail are 4.2 mm wide. The system provides secure proximal and distal locking, ensuring maximal stability, with minimal risk of screw breakage.

Indications
- Diaphyseal fractures
- Impending pathologic fractures
- Nonunion or malunion

Contraindications
- Intra-articular fractures of the proximal or distal tibia
- A medullary canal obliterated by a previous fracture or tumor
- Bone shaft having excessive bow or deformity
- Active infection
- Lack of bone substance which makes stable seating of the implant impossible
- Allergy to the implant material
- Patient conditions including blood supply limitations, and insufficient quantity or quality of bone

Features & Benefits
- Minimal invasive technique and biomechanical stability allow early functional exercise
- Accurate and fast mechanical aiming device for proximal and distal locking
- Type II anodized Titanium Alloy for enhanced biomechanical and biomedical performance
- Implants also available in Stainless Steel
Surgical Technique

Step 1. Pre-operative planning
The surgeon should be able to gain a good estimate of the required length pre-operatively, by direct measurement of the length of the tibia from the plateau to the medial malleolus, if necessary, using the uninjured leg. By looking at the width of the medullary canal on the radiograph, and from the knowledge of the weight of the patient and the severity of the fracture, the surgeon will be able to gauge the likely diameter of the nail, and whether to use a reamed or an unreamed nail. It should be noted that the X-ray film has magnification of 8% or 15%. A larger nail is indicated in severely comminuted diaphyseal fractures and in proximal third fractures to provide extra stability. In general, the size of nail chosen will depend on the size of the bone, and the amount of reaming, if any, that the surgeon is prepared to accept.

Step 2. Preparation of the patient
Position the patient supine on a radiolucent operating table. Ensure that the knee of the injured leg can be flexed at least 90° and x-ray visualization of the entire tibia is possible in both the AP and lateral views. Temporary reduction and stabilization can be accomplished by manual pressure at the fracture site. Or by application of a sterile tourniquet or elastic bandage around the fracture. Alternatively, reduction can be achieved by skeletal traction with Steinmann-type pin inserted through the os calcis. At the surgeon’s discretion, the procedure can be performed on a fracture table with the leg placed in traction.

Step 3. Insertion site
The entry point for the nail is in line with the medullary canal in the AP view, and is at the anterior edge of the tibial plateau. The location of the entry point in relation to the tibial tubercle varies with patient anatomy. Make a longitudinal incision over the midline of the tubercle, extending proximally. Retract the patellar tendon laterally, or split the tendon, depending on surgeon preference and patient anatomy.
Surgical Technique (Continued)

The tip of the Pointed Awl is placed at the entry point and the Image Intensifier used to confirm that this is centered over the canal. If it is not, it is adjusted until it is satisfactory, checking the position of the tip of the awl in the medial-lateral plane. The awl is then advanced with a rotational action towards the medullary cavity, keeping the straight part of the handle parallel with tibial diaphysis, so that the tip of the awl is pointing directly down the tibial shaft.

The awl is removed, and at this point it is useful to confirm that the medullary canal has been opened, using the 7mm Rigid Reamer, which is gently pushed down into the medullary canal. The introduction of the Rigid Reamer should be stopped as soon as resistance is felt. With the Rigid Reamer in place, the Image Intensifier should now be used to confirm alignment in both planes. The entry portal is opened to 9 mm with the larger Rigid Reamers, and is now ready for the insertion of an unreamed nail, off for a guide wire prior to reaming, as described below.

It should be emphasized that the Rigid Reamers are not designed to ream cortical bone, and no attempt should be made to ream the isthmus with these instruments. If the central part of the medullary canal is not wide enough, power reamers should be used to enlarge it as necessary described on page 12.

Step4. Reaming procedure
If an unreamed nail is to be inserted, ignore the following section on reaming, and proceed to the section on Nail Insertion-unreamed Nail.

Guide Wire Insertion
Throughout this procedure, care should be taken to retract the patellar tendon away from the operating field, to avoid damaging it and to use the Skin Protector to avoid bruising the articular surface of the patella, or the overlying skin, The Guide Wire with Olive is now inserted through the hole and passed along and through the proximal fragment. Once the proximal end of the fracture line has been reached, the Guide Wire is manipulated in such a way that it reaches the distal fragment. A bend in the tip may be necessary to allow the surgeon to control the direction of insertion by turning the wire. In difficult cases, it is useful to attach a Gripper on to the proximal end of the wire for additional control. Guide wire insertion must be carried out under image intensification in two planes. In mid-shaft fractures, the path of the Guide Wire is dictated by the contour of the medullary canal and this may help to prevent valgus or varus displacement of the distal fragment. The Guide Wire is inserted until its tip sits 0.5-1cm proximal to the ankle joint, care being taken to ensure that it is exactly in the midline. The Gripper should be removed leaning the Guide Wire.

The medullary canal is now reamed by passing reamer over the Guide Wire, always starting with the 7.5mm reamer. Reaming should be continued in 0.5 mm increments before the medullary canal is reamed to 9mm. After that, the reaming should be continued in 1.0mm increments, up to a width 1-2mm greater than the nail diameter, 1 mm normally being sufficient. The Skin Protector should be used proximally. Reaming past the isthmus is generally sufficient except in the case of a distal fracture, where reaming should be extended beyond the fracture line.

Steady pressure should be exerted while reaming and a check should be made that the reamer is advancing at all times. Excessive pressure, or a reamer that is not advancing, may indicate that the reaming head has become clogged with bone debris. It is very important in these cases to remove the reamer and clean the head. In young patients with hard bone this may be necessary more than once. If the reamer will not pass easily in spite of cleaning the head, it should be removed, and the previous size inserted, and passed slowly up and down the canal twice. A check should also be made to ensure that the reaming heads are being used in the correct order. A reamer that is not advancing for any reason may cause significant thermal damage to bone and soft tissues. The reamer may jam if the power is turned off while it is in the canal, and this should be avoided.
Surgical Technique (Continued)

Step 5. Nail insertion

Reamed Nail

The plastic Guide Wire Exchange Tube is inserted over the Guide Wire with Olive, so that it is well across the fracture site. Holding the tube in place, the Guide Wire is now removed, and the Guide Wire is inserted. After confirming that the tip of the Guide Wire is in the correct position, the plastic tube is removed for insertion of the cannulated nail.

For solid nails, directly insert the nail following below description after removing the Guide Wire with Olive.

A nail of correct diameter and length is now selected. The Locking Rod is inserted into the back of the Nail Support Handle and the chosen nail into the nail support.

The nail must be rotated until it seats into the correct position and the Locking Rod is then firmly tightened into the nail, completing this with the SW 5 Wrench. Before the nail is inserted, it is important to check alignment of the distal and proximal holes in the nail and the Guide Bar. In order to do this, the Guide Bar is mounted on to the handle following the procedures described below under “Distal Locking” and “Proximal Locking” pages.

The nail is now manually inserted over the Guide Wire into the medullary canal as far as possible, under image intensification. The nail is advanced into the distal fragment until the step on the nail support is flush with the surface of the bone. This indicates that the nail has been inserted to the correct depth. Ideally, the nail should be inserted by hand, but gentle tapping may be necessary.

Note:

-Remove the Guide wire prior to drilling holes and insert the Locking Screws.

The Sliding Hammer maybe attached to the end of the nail Locking Rod, and it must be tightened fully to avoid damage to the thread. The nail can then be inserted into the correct position by gentle hammering. Ideally, the proximal end of the nail is recessed in the bone by 10-15 mm. If the nail will not advance, it should be removed, after replacing the Guide Wire, and the bone reamed an additional 1.0 mm. If this is unacceptable, a smaller diameter nail should be inserted.

Note:

-After the Sliding Hammer has been removed, a check should be made to ensure that the Locking Rod is tightened firmly.

Unreamed Nail

It is always preferable to use a 9 mm nail if possible. The 8 mm or 9 mm nail is locked firmly to the Nail Support Handle with the Locking Rod as for the reamed nail. It is then inserted through the entry portal into the medullary canal, and advanced manually as far as possible, using X-ray control. It will normally be necessary to attach the Sliding Hammer, as described above, to complete the insertion, hammering as gently as possible.

Care should be taken to ensure that the nail remains parallel to the tibial diaphysis, to avoid perforation of the cortex. If the nail will not pass in spite of hammering, the situation should be carefully reviewed with the Image Intensifier. The tip of the nail may be striking the posterior cortex. In this case the nail should be removed by reverse hammering, and the direction of the entry portal adjusted. If the nail will not pass, but the direction seems to be correct, it should again be removed, and consideration given to using a smaller nail, or to reaming.

At the end of insertion, the fracture site should be checked by X-ray to see whether nail insertion has caused any distraction of the fragments. Distraction at the fracture site for any length of time may be associated with compartment syndrome, and must be avoided. If at all possible, and distraction should be corrected now by compression between heel and knee. If full correction is not achieved at this time, it can be affected following distal locking, which in this case must be done first. It is also important at this stage to check for axial reduction in the sagittal and coronal (frontal) planes.

Note:

-Both reamed and unreamed nails can be advanced by gentle rotational movements until the bend in the nail reaches the surface of the bone. After this the nail must be advanced without rotation by pushing or hammering.
Surgical Technique (Continued)

Step 6. Distal locking
It is generally recommended that distal locking is performed first, because it is potentially more difficult. In very proximal or unstable fractures, however, it may be preferable to carry out proximal locking first.

The Guide Bar is introduced into the handle, moved downwards until the number corresponding to the nail length is at the level of the front of the handle, and locked firmly into place. Note that there is a depression for the tip of the Bar Locking Screw corresponding to each nail length. A retaining ball in the handle makes finding the correct position of the Guide Bar easy. The distal locking screws are inserted in the frontal plane, normally from the medial side. On rare occasions, because of skin damage medially, or because of the configuration of a distal fracture, the surgeon may wish to insert the screws from the lateral side. In this case the Distal Otrigger is placed on the lateral side, and the nail is rotated so that the locking screws will pass anterior to the fibula. The procedure for distal locking is then identical to that for the more usual medial approach.

The Distal Otrigger is mounted on the Guide Bar so that it lies on the correct side of the tibia, and the Screw Guides are inserted into the Otrigger, but no incision is made as yet. The system is first stabilized in exact alignment, utilizing the Stabilizing Rod.

A Drill Guide (Ø7/Ø4) is inserted into the holes in the Distal Otrigger Locking Screw. An incision is made in the skin directly beneath it, and the anterior tibial cortex exposed by blunt dissection using the Obturator, taking care to deflect the tendon of Tibialis Anterior laterally to avoid damage to it or to the neurovascular bundle. The Drill Guide (Ø7/Ø4) is advanced until its tip is engaged in the tibia, and stabilized on the center of the tibial crest. A 4 mm Drill Bit is now used to drill the anterior cortex only. The Drill Bit is removed. A Pin (Ø4) can also be used to drill a recess on the tibial cortex before using Drill Bit to increase its stability.

The square ended 4mm T-handled Reamer is passed down the drill guide, and used to complete the hole down to the nail, and to remove intervening debris. It should be possible to feel and hear the tip of the reamer touching the nail. The T-handled Reamer and Drill Guide are now removed, and replaced by the Stabilizing Rod, which is inserted through the anterior cortex down to the nail, again gently tapping it on to the nail to confirm that there is no intervening debris.

The Stabilizing Rod must now be fixed in an exact position according to the diameter of the nail, and this is achieved by clipping the appropriate U-Shaped Stabilizing Spacer on to the Guide Bar, so that its forks engage the two recesses in the Stabilizing Rod. The three spacers are each calibrated for two nail diameters, with a figure from 8 to 13 engraved on each side. A spacer should be positioned so that the correct nail diameter is visible on the upper surface, facing towards the surgeon.
Tibia Nail System

Surgical Technique (Continued)

As with all distal locking procedures, the surgeon’s drilling technique is vital to the success of the procedure. It is important that the drill is held securely in line with the Drill Guide (Ø8/Ø4), avoiding any bending of the drill bit. Excessive force should be avoided, so that the surgeon can “feel” the drill passing through the bone and the nail. If the drill has a pistol grip, it is very important that the force applied during drilling is axial to the drill bit, and directly in line with it. Pressing on the handle of this type of drill causes a bending force to be transmitted to the drill bit, and this may be sufficient for it to miss the holes in the nail.

The assistant maintains constant contact between the tip of the Stabilizing Rod and the nail throughout this procedure, if necessary, by applying gentle pressure. The Drill Guide (Ø8/Ø4) is inserted into one of the Screw Guides and gently tapped to engage the tip in the cortex. The surgeon continues to hold the the Drill Guide (Ø8/Ø4) with one hand until the first cortex has been drilled.

The Drill Stop is attached to the Drill Bit at the proximal end. The Drill Bit is introduced into the Drill Guide (Ø8/Ø4), down to the bone, before the drill is started, and gently pressed to engage the tip in the cortex.

The surgeon now drills steadily through the near cortex, and stops when the second cortex is reached. The Drill Stop is moved down until it is 7-10 mm above the top of the Drill Guide (Ø8/Ø4), and locked into place. This represents the thickness of the second cortex. Drilling now continues through the second cortex. The Drill Stop prevents damage to the tissues beyond the bone, and also provides a method of estimating the correct length of the locking screw.

The assistant now exerts gentle pressure on the T-handle of the Stabilizing Rod, so that its tip is pressed against the nail. This ensures that the distance between nail and Guide Bar is constant, allows for any deformation of the nail in the sagittal plane, and maintains the alignment for the distal targeting. It also stabilizes the Guide Bar and Outtrigger, so that the surgeon has a secure platform for drilling the distal holes. It is possible, if the assistant presses too hard, for the tip of the Stabilizing Rod to be pushed past the nail. Normally, gentle pressure only is required, and the assistant should be able to feel the contact between the tip of the Stabilizing Rod and the nail at all times. On occasion, a gentle UPWARD or DOWNWARD pressure may be necessary to ensure that the tip of the Stabilizing Rod remains in contact with the anterior portion of the nail.

An incision is now made beneath each Screw Guide, and the cortex exposed in each incision by blunt dissection, taking care to avoid entrapment of, or damage to, the neurovascular structures. Similarly, if the approach is from the lateral side, the surgeon must ensure that the tendons and vessels are not damaged during the locking procedure, by careful soft tissue dissection down to the bone. The Screw Guides are then advanced until they are in contact with the cortex, and the Clamp Locking Nut on the Outtrigger tightened to hold them firmly in place.
Surgical Technique (Continued)

The Drill Bit is removed with the Drill Guide (Ø8/Ø4). The Graduated Angled Trocar is now inserted into the Screw Guide, so that it passes through the nail, and engages the far cortex. This trocar should now have stabilized the position of the Guide Bar and Outrigger in relation to the nail, and its position can be confirmed by manipulation or with the Image Intensifier. Now that Screw Guide alignment is maintained by this trocar, the assistant may release the T-handle of the Stabilizing Rod.

The appropriate locking screw length, from the top of the screw head to its tip, is determined by measuring the amount of drill bit protruding from the Drill Guide (Ø8/Ø4), and then add 5mm to it. The tapered tip of the Drill Bit should be ignored in this measurement. A screw of the correct length is reserved. An alternative method of screw measurement using the Depth Gauge is described below.

The Tap is inserted into the Screw Guide to tap the proximal cortex. There are three circular marks on the Screw Tap which indicate the depth of tapping are 6, 8, 10mm according to the length of a locking screw's thread. The Screw Tap is removed. A locking screw of correct length is now inserted into the second Screw Guide, and pushed through the bone with the Hex Screwdriver, until its thread engages the cortex. Note that there is a circular mark on the Screwdriver Shaft. This mark will be 6-10 mm above the top of the Screw Guide when the locking screw has been pushed in sufficiently. There is no point in turning the Screwdriver until this position is reached, because there will be no thread in contact with the bone. The Screwdriver is now turned steadily clockwise, exerting gentle pressure, until the mark on the shaft of the Screwdriver reaches the top of the Screw Guide. One more complete turn should then be made to tighten the screw fully. It is important not to continue turning after this position is reached, because the thread in the bone may be stripped.

The assistant again holds the Stabilizing Rod, and the Graduated Angled Trocar is removed from the first screw guide. The same technique is followed for insertion of the second distal locking screw, after which both Screw Guides are removed by loosening the Clamp Locking Nut. A check should now be carried out with the Image Intensifier or radiograph to confirm that both locking screws have passed through the nail and to confirm that the reduction has been maintained. The Distal Outrigger and the Stabilizing Rod are now removed.
Surgical Technique (Continued)

Alternative Method of Estimating

If there is any doubt about the correct locking screw length, either in respect of the measurement obtained after drilling, or because the surgeon omitted this step, the locking screw Depth Gauge may be used as follows: the surgeon should first check that the screw guide is positioned so that it is touching the bone. The Depth Gauge cover is then unscrewed and removed. The hooked end is inserted down the Screw Guide and through the bone. It is then drawn back so that the hook engages the outer surface of the far cortex. The correct length of screw can now be read at the top of the Screw Guide. This Depth Gauge is only suitable for use with Tibial and Femoral Nails, since its accuracy depends on a fixed length of Screw Guide.

Step 9. Proximal locking

The Guide Bar Locking Screw is loosened, and the bar moved until the Zero mark is level with the front surface of the handle, where it is locked into position. The Proximal Outrigger is mounted on the bar, and two Screw Guides inserted into the guide seats to locate the sites for the incisions. Before making the incisions, the surgeon should carry out a final check for reduction of the fracture, remembering the possibility of distraction. An incision is made beneath each Screw Guide, and the tibial cortex exposed in each case by blunt dissection. The Screw Guides are advanced down to the cortex and locked in position with the Clamp Locking Nuts. The medial hole is drilled first.

A Drill Guide (Ø8/Ø4) is inserted into the medial Screw Guide, and tapped gently to engage its tip in the cortex. The Drill Bit is introduced down to the bone, and pressed against the cortex to fix the tip before drilling begins. The Graduated Angled Trocar is inserted after this hole is drilled, and final alignment confirmed. The lateral hole is now drilled, the screw length determined, the proximal cortex tapped and the screw inserted. The Graduated Angled Trocar is then removed, and the medial screw inserted using the same technique.

Step 8. Check for fracture distraction

Before proximal locking is carried out, the fracture should be screened to check for any distraction. If this is present, the Sliding Hammer can be reattached to the locking Rod as described previously. The fracture gap can then be closed by gentle reverse hammering, after which the hammer is removed. It is very important to avoid completing the locking of the nail with the fracture distracted. There is an association between fracture distraction, and delayed union or compartment syndrome.

Step 10. Final Check

A final check is now made to confirm that fracture reduction is satisfactory, and that all four locking screws are correctly inserted through the nail, the screw heads flush with the bone, and the distal ends just protruding beyond the second cortex.
Tibia Nail System

Surgical Technique (Continued)

Step 11. Removal of the jig assembly and closure
The Proximal Outtrigger is removed, the Guide Bar Locking Screw loosened, and the Guide Bar removed. At this stage, the Handle is removed after loosening the Locking Rod a few turns with the SW 5 Wrench. Once the Locking Rod and the Handle have been removed, a Nail End Cap is placed over the end of the nail. The nail end cap is screwed tight with the Hex Screwdriver. Closed suction drainage is advised for the insertion wound. All incisions should be sutured in layers in the usual way. Firm dressings should be applied to prevent hematoma formation. The drainage is removed after 24-48 hours.

Post-operative Management

Step 1. Weight bearing
The patient is mobilized on crutches immediately, but the knee is rested in an immobilizer for 1-2 days. Dressings are changed daily, and after the drain has been removed, the knee may be mobilized freely. With a stable fracture, a patient may weightbear as able, increasing to full Weight Bearing by 4 weeks. If the fracture is unstable, toe touch weightbearing is permitted immediately, with gradually increasing partial weightbearing over the next 6 weeks. Full weightbearing is only advised once there is some continuity of callus across the fracture site. Fractures with severe comminution, of Winquist-Hansen types IV and V, should be supported before weightbearing with an external brace, if an 8 mm or 9 mm nail has been used, until the fracture is healed.

Step 2. Dynamization
Dynamization, by removal of one pair of locking screws, is not recommended as part of the standard technique. However, should there be no callus formation at 12 weeks, removal of the pair of screws furthest from the fracture site is advised, provided that the fracture is stable. If the fracture is unstable, exchange nailing with a larger reamed nail should be considered. The surgeon should try to avoid continued fixation with an 8 or 9 mm nail if delayed union is present. In this situation, exchange nailing with a larger diameter cannulated nail is preferable. If the fracture site looks atrrophic, further local measures to encourage union may be needed.

Step 3. Resumption of normal activity
Patients employed in light work or in an office may resume their job as soon as they are fully comfortable, assuming that the state of the soft tissues is satisfactory. Patients in work that is heavy or involves potentially dangerous situations should not be allowed back before the bone is radiologically united, and this is rarely less than six months after the injury.

Step 4. Nail removal
Nail removal may normally be carried out after 18-24 months provided that there is radiological evidence of union. Union may be expected to occur after 6 months with nailing procedures in the tibia. The situation may be different in open fractures, non-unions or corrective osteotomies. In such cases the nail should be left in situ for a minimum of 24 months. The proximal end of the nail is exposed through a small incision. It may be necessary to clear some new bone from the end of the nail. The nail end cap is removed with the Hex Screwdriver, and the Screw Adapter is screwed on to the nail, and tightened firmly. This should be accomplished prior to the removal of the proximal locking screws to prevent the nail from deflecting posteriorly.

The locking screws are now all removed. When locking screws require to be removed for any reason, (e.g. nail dynamization or extraction, or in the occasional case where the length of the chosen locking screw is incorrect), this maybe accomplished using the Locking Screw Extractor as follows: the Extractor is inserted down to the head of the screw, and is turned counterclockwise. The thread on the outside of the locking screw head is a verse thread, so it is necessary to turn the Extractor counterclockwise throughout this procedure. The first turns lock the extractor to the screw head, and further turns will release the screw thread from the bone. Once the thread has been disengaged from the cortex, the screw should be pulled out directly. Further turns at this point will achieve nothing, as no thread remains in the bone. Note that the locking screw is then disengaged from the extractor by turning the latter clockwise, which is the opposite direction to normal. It may be necessary to grip the smooth shaft of the screw with forceps during this procedure.

The nail is then removed, either by manual traction on the Screw Adapter, or by reverse hammering, after screwing the Sliding Hammer on to the proximal end of the adapter.
Tibia Nail System

Implants Ordering Information

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4mm Locking Screw

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End Cap

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