

Intramedullary Skeletal Kinetic Distractor Tibial Surgical Technique

By J. Dean Cole, M.D.
with contributions to Pre-Operative Planning from Dror Paley, M.D.
and to Radiographic Technique from Mark Dahl, M.D.

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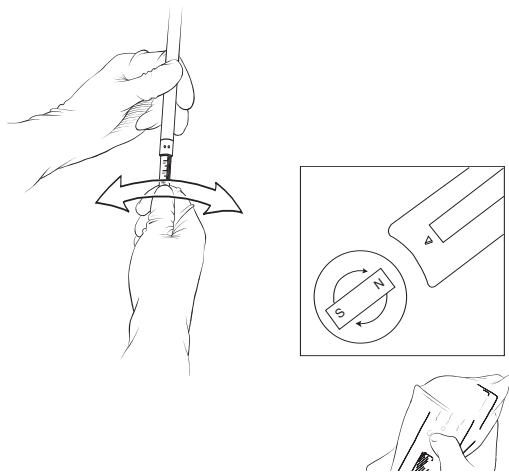
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Femoral ISKD



Tibial ISKD



Pre-Insertion Distraction and Functional Check

- 1 Prior to inserting the ISKD, set its length to the amount determined during preoperative planning, with small back-and-forth rotations of the distal section relative to the proximal.
Note: Do not distract the device too far. The ISKD will only distract and distractions cannot be undone.

Check the integrity of the magnet using an ISKD monitor that has been placed in a double sterile bag.

Turn on and reset the monitor, and place it just above the Key Ring at the distal end of the proximal section. Rotate the entire lengthener slowly until the monitor signals two changes in polarity.

Venting

- 2 Drill one or two 6 mm diameter holes in the distal tibia, across one cortex and into the intramedullary canal. Position vent below the most distal end of the ISKD (when inserted). Insert a hollow cannula into the hole so that the tip of the cannula is flush with the intramedullary cortical surface, but not protruding into the intramedullary canal. Clear the cannula frequently with a guide wire during the procedure, to ensure an uninterrupted flow of intramedullary contents.



Osteotomy

- 3 Create an osteotomy at the junction of the upper and middle 1/3 of the tibia, for maximum stability of the ISKD and optimal biomechanical conditions for activation of the lengthening mechanism.

Note: DO NOT perform the osteotomy in the proximal or distal metaphyseal areas, where the larger intramedullary canal diameter may lead to instability of the distracted fragment, and higher bending moments will result in excessive loading of the ISKD.

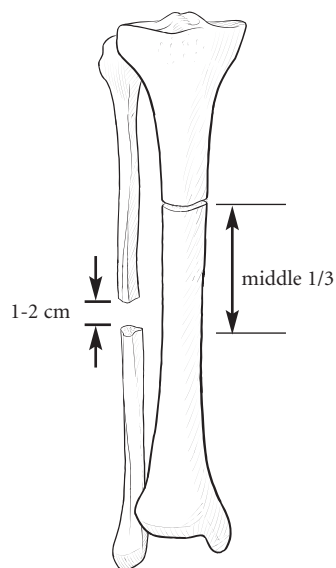
Perform the osteotomy either:

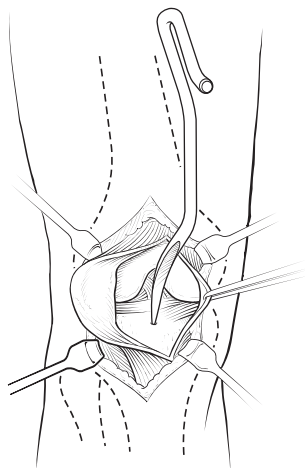
- 1) with an intramedullary saw, or
- 2) with an osteotome through a small incision. Preserve the periosteum to protect the blood supply to the regenerate bone by separating it with a periosteal elevator; or
- 3) by drilling a series of small holes in the bone and connecting them with an osteotome.

The posterior cortex may be difficult to cut and may be broken through osteoclasia by rotating the limb. Assure fragment shape allows easy rotation.

ALWAYS REMOVE 1-2 cm of the lower middle third of the fibula to allow the ISKD to distract. Fix the distal fibula to the tibia with a syndesmosis screw.

The osteotomy should be smooth and transverse to allow easy rotation. As it is imperative that the two bone segments rotate freely and independently of each other, it is important to perform a rotation test after the osteotomies are complete.

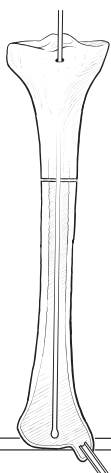




Insertion Site

4 Anterior Approach

The entry portal must be very proximal, no more than 1 cm distal to the anterior edge of the tibial plateau. A more distal entry point may result in damage to the posterior cortex. The awl, or cannulated cutter over a guide wire, is used to open the medullary canal in the midline, keeping the straight part of the shaft of the awl parallel to the long axis of the tibial shaft. An Image Intensifier check in both the sagittal and frontal planes should confirm that the tip of the awl or guide pin is in the line of the tibial canal.



Reaming

5 Open the medullary canal in the midline, keeping the straight part of the awl parallel to the long axis of the tibial shaft.

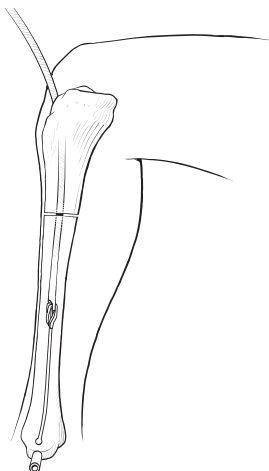
Check with the image intensifier in both planes that the tip of the awl is in line with the tibial canal.

Use a 7 mm Rigid Reamer to reach the medullary canal, and confirm alignment.

Enlarge the entry portal with rigid reamers to 9 mm.

Insert the guide wire until its tip sits 0.5 –1.0 cm proximal to the ankle joint, ensuring that it is exactly in the midline.

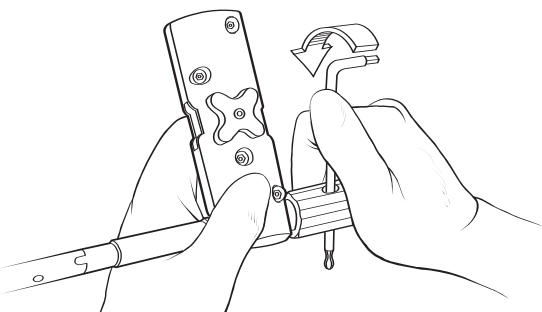
0.5 - 1.0 cm



6 Ream to a width of 1.5-2.0 mm greater than the proposed lengthener diameter.

Ream past the isthmus, as it is important that the ISKD does not fit too tightly in the intramedullary canal and to permit the rotational movement required for function of the lengthening mechanism.

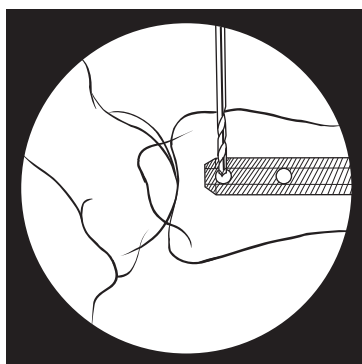
When reaming is complete, remove the guide wire and irrigate the incision with normal saline to remove all bone fragments.



Lengthener Insertion

- 7** Insert the Locking Rod through the handle into the lengthener, and tighten it with the 4 mm Allen wrench.
- Tap the ISKD into place. It must not be rotated or twisted, and must not be vigorously hammered.

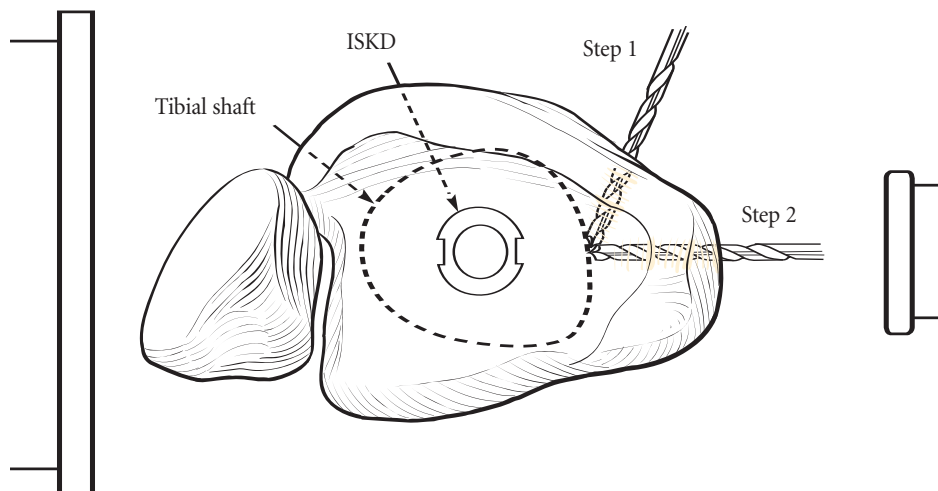
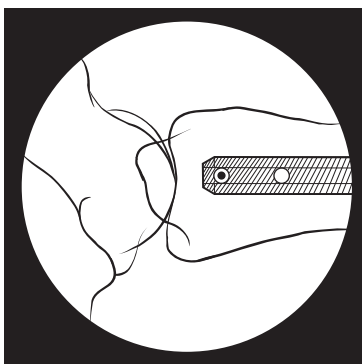
Step 1

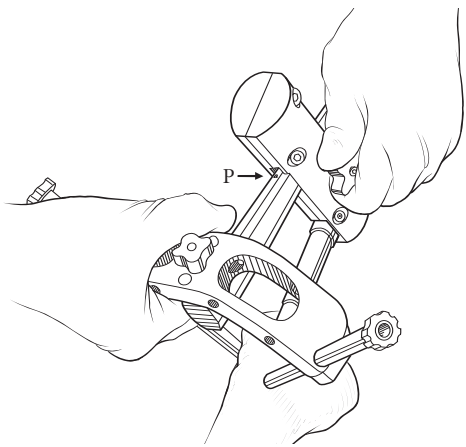


Distal Locking

- 8** Use the freehand technique for distal locking, preferably with a radiolucent drill.
1. Obtain a lateral image so that the locking holes are seen as true circles.
 2. Locate the position for the skin incisions. Make small stab wounds and penetrate with blunt dissection down to the bone.
 3. Place the tip of the drill bit on the bone in the center of the circle as viewed on the fluoroscope.
 4. Orientate the drill bit so that it also appears as a small dot in the center of the circle.
 5. Advance the drill bit through both cortices and insert the locking screw.
- Note: It is very important for biomechanical stability that two proximal and two distal locking screws are used.

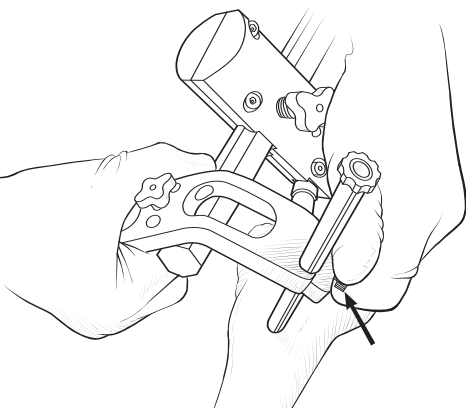
Step 2



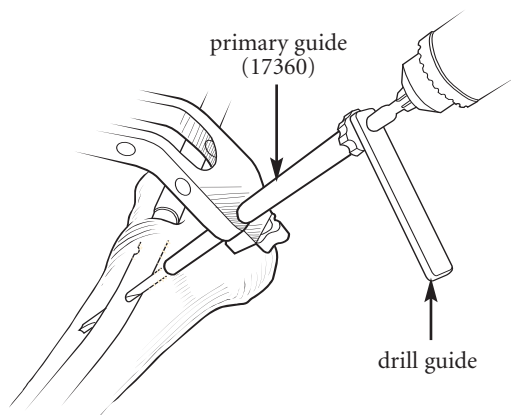


Proximal Locking

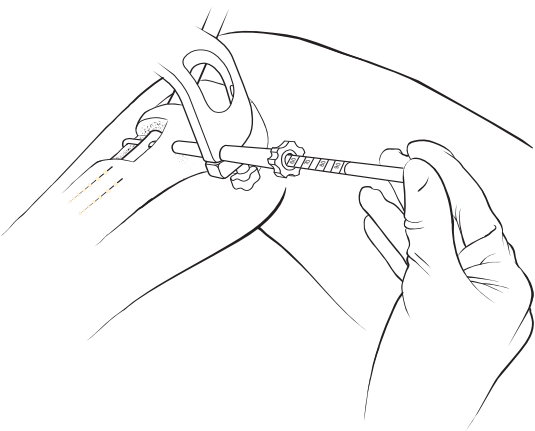
- 9** Prior to proximal locking, perform image intensifier check of osteotomy site. Assure intended gap is present to allow the two bone segments to rotate freely and independently of each other.
- May need to impact proximal lengthener to ensure gap is present.
- The amount of fracture osteotomy gap necessary to ensure easy rotation is dependent on fragment geometry.
- Loosen the guide bar locking screw.
- Insert the bar until the P mark is level with the front surface of the handle, and lock it into position.
- Mount the proximal outrigger and insert two screw guides (17360).



- 10** Make an incision beneath each screw guide.
- Expose the tibial cortex on each side by blunt dissection.
- Advance the screw guides down to the cortex and lock them in position.



- 11** Insert an intermediate screw guide (11124) into the primary screw guide (17360). Insert a 4.8 mm drill guide medially, and tap it gently to engage the teeth of the screw guide in the cortex.
- Drill this hole first through both cortices.
- Remove the drill bit, drill guide and intermediate screw guide.



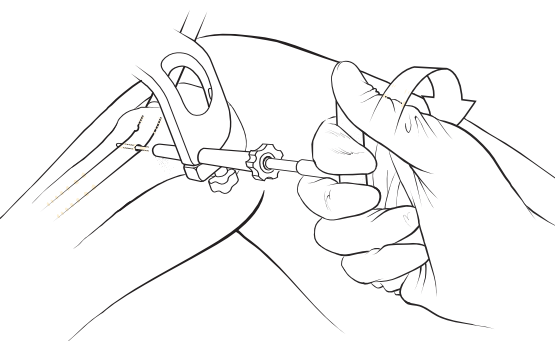
12 Check that the end of the screw guide is touching the bone.

Insert the depth gauge and engage the hook on the far cortex.

Read the correct length of locking screw at the top of the screw guide.

Insert a locking screw of correct length; push it through the bone with the screw T-wrench, until its thread engages the medial cortex, at which point the circular mark will be 7-12 mm above the top of the screw guide.

Do not drill the second hole before inserting the locking screw.



13 Turn the T-wrench clockwise, with gentle pressure, until the mark on the T-wrench reaches the top of the screw guide.

Make one more full turn to tighten the screw fully. Do not continue turning after this point, or the thread in the bone will be stripped.

Drill the second locking hole using an identical technique and insert the second locking screw.

Loosening the guide locking screws and remove both screw guides. Remove the guide bar from the handle.

Check that the osteotomy is not distracted.

In the O.R., perform a limb rotation test to assure the limb rotates freely.

Removal of Jig Assembly

Remove the proximal outrigger and guide bar.

Remove the handle after loosening the locking rod a few turns with the 4 mm Allen wrench.

Insert the Lengthener End Cap, and screw it tight with the T-wrench.

The ISKD combines the advantages of intramedullary stabilization with the mechanics of external distraction. Since the ISKD is completely internal, the potential risk of infection is reduced compared to lengthening procedures that require external fixation pins or wires. The ISKD is designed to lengthen gradually as a result of deliberate movement between the segments of bone separated by the osteotomy. Rotational movement as small as 3° causes distraction; however, movement as great as 9° is possible if less frequent movement of greater magnitude is preferred. Because the ISKD is designed to lengthen for a predetermined distance and then stop, the starting and final lengths of the ISKD required to achieve the desired amount of distraction of the limb must be carefully planned preoperatively.

The recommendations in this surgical technique should serve as a guide for the use of the ISKD. The recommendations should be tempered by the judgment and technical expertise of the individual surgeon.

Cautions:

- 1) Accurate pre-operative planning is a requirement of the procedure to determine leg length discrepancy and ultimate goal length of the procedure.
- 2) Meticulous attention to surgical detail is needed.
- 3) Patient selection is critical to the success of the operation.
 - The patient must be able to achieve 3°-9° rotation at the knee for distraction to occur.
 - Patient must be able and willing to weight bear no more than 50 lb (22 Kg) toe touching during the entire Distraction Phase and through most of the Consolidation Phase. The device cannot withstand the forces of full weightbearing.
 - The ISKD should never be used for lengthening if the epiphyses have not fused. It is therefore only suitable for patients where the growth plates have closed.
 - Patients with non-unions, massive obesity, obliterated or irregular intramedullary canals, malignancy or tumor of the affected bone, poor bone quality or metabolic bone disorders, active infections, unresolved poly-trauma, peripheral vascular disease, or cardiac pacemakers may not be appropriate candidates.
 - Smoking, chronic steroids and anti-inflammatory drugs may have a detrimental effect on the regenerate quality.
 - Patients who are unable or unwilling to comply with the post-operative instructions are poor ISKD candidates.
- 4) Patients who undergo ISKD implantation must be warned that they should not undergo MRI procedures while the device is implanted.

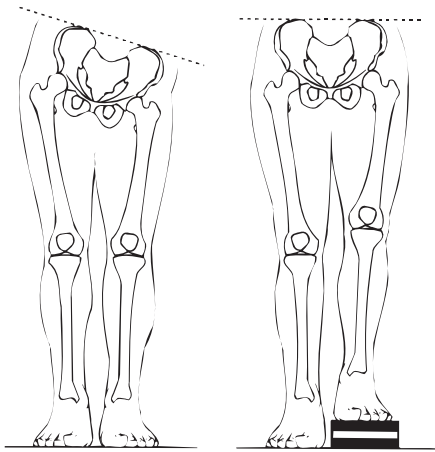


Figure 1

Measurement of Limb Length Discrepancy

Limb length discrepancy is measured by two methods, a clinical method and a radiographic measure. There should be a correlation between the two.

The Clinical Technique

The first is a clinical examination where the patient is standing shoeless, in the office, with a series of polyethylene blocks placed under the short limb until the pelvis both appears and feels level to the examiner (Figure 1). The foot should be positioned so that each patella points forward. This may require rotation of the foot (Figure 2). The thickness of the block under the shorter limb is recorded as the clinical leg length discrepancy. If the patient has a significant foot positional deformity, preventing plantigrade position of the foot, the block may be placed underneath the plantigrade portion of the foot (such as the heel pad). Alternatively, a measurement from the anterior iliac spine to the medial heel pad can be performed. It is important to be able to measure limb length discrepancy to within about 0.5 cm using the blocks.

X-ray Technique

The second method, which is more precise, is through the use of weight-bearing long leg radiographs. The X-ray technician performs a similar test with the blocks until the pelvis appears and feels level. The full-length standing AP X-ray is then performed standing on blocks as described above.

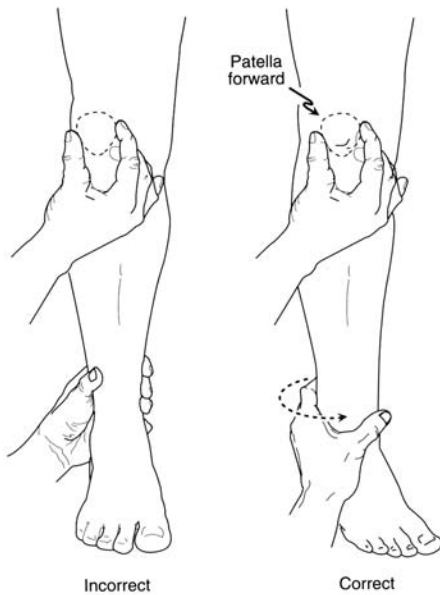


Figure 2

Full-length standing antero-posterior (with hips parallel and block under short limb) and lateral views, should be taken of both the affected and unaffected limbs. The radiograph must use a method to account for magnification, such as an X-ray marker ball at the level of the hip or full-length ruler. The height of the block should be documented on the radiograph. An X-ray is taken to establish the original length of the affected tibia, the diameter of the intramedullary canal and the length of the unaffected tibia. Measurement of limb angles, and anatomic and mechanical axes, is also performed preoperatively to document contractures or deformities. Two measurements from the radiographs are then performed.

- 1) The first measurement determines individual bone segment lengths. Reference lines are drawn at the top of the femoral head, the bottom of the femoral condyle, top of the tibial plateau, and the bottom of the tibial plafond. Each limb segment length is then determined by measuring along the mechanical axis between each reference line. Correction for magnification should be used in calculating these measurements.

Figures 1, 2, 3 are from: Paley, D., Herzenberg, J.E., Tetsworth, K., McKie, J., Bhav, A. *Deformity Planning for Frontal and Sagittal Plane Corrective Osteotomies*. Orthopaedic Clinics of North America, 25:3, 1994

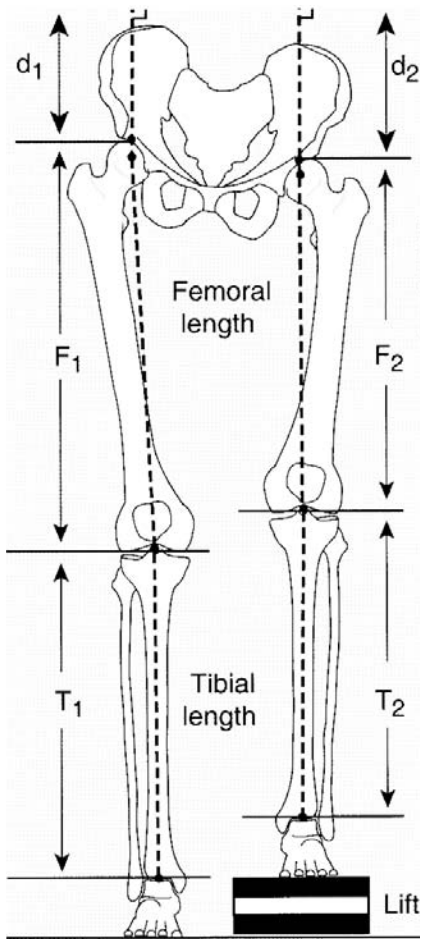


Figure 3

2) The second measurement is performed to measure overall limb length discrepancy. The distance from the top of the X-ray film to the femoral head reference line is measured for each limb, and the relative difference is determined (d_2-d_1), again correcting for magnification. This difference (d_2-d_1) is then added to the height of the block that was placed under the shorter limb and produces the total Limb Length Discrepancy. (Figure 3)

Alternative radiographic methods for determination of limb length discrepancy are available, but are not optimal.

- 1) Scanograms may be less useful because some are taken with the patient non-weight bearing and limb alignment cannot be determined.
- 2) Separate films of the bones are not recommended as a means of determining limb length discrepancy since magnification will vary and limb alignment cannot be determined.

Magnification Error

X-ray magnification varies from 3% to 12% but should be standardized to 3% to 5% using the protocol which follows. The X-ray must include a means of accounting for magnification, such as a ruler or standard radio-opaque device of known diameter in the center of the field. All determinations of limb length discrepancy using the radiographic technique must account for magnification errors.

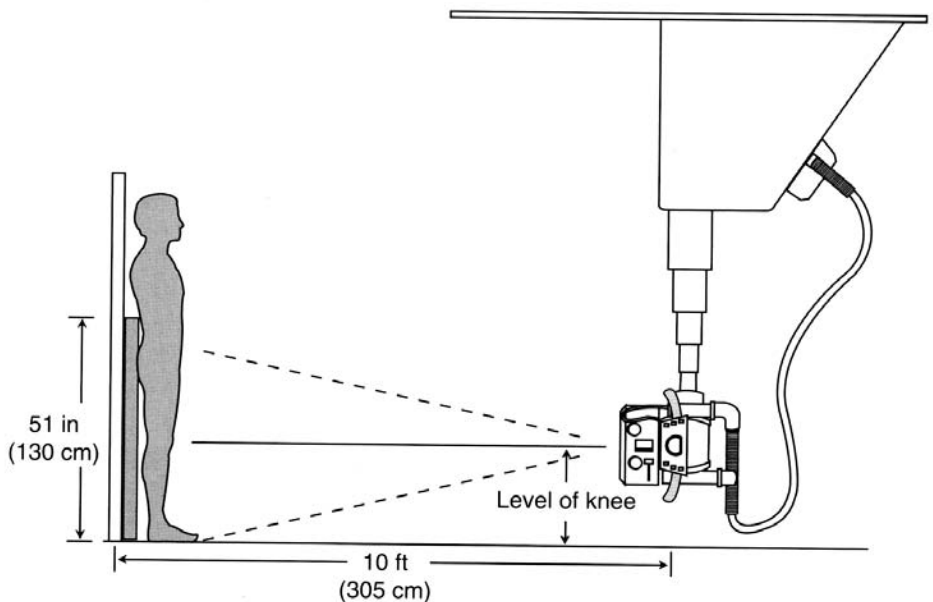


Figure 4

Procedure (Figure 4)

1. Load the cassette in the holder.
2. Ensure that the cassette is inserted in correct direction.
3. Center the film over the object to be X-rayed.
4. Position patient, keeping the following in mind:
 - a. The patient should be 10 feet away from the X-ray tube (Figure 3).
 - b. The kneecaps must be facing forward (Figure 2).
 - c. Weight should be distributed equally on both feet. A lift may be inserted if necessary (Figure 1)
 - d. The patient must be shielded.
 - e. The patient should hold onto the lead shield, keeping the hands at chest level.
5. Insert a filter in front of the X-ray tube.
6. Take the X-ray.

Technique Specifics

Kilovolt Peak (KVP): To achieve adequate part penetration throughout the range of variable subject size and density for the part, an adequate KVP should be utilized for the given body part. To maintain image contrast throughout the range of the study, the same KVP should be utilized at all times for the given body part.

Suggestion: For the ISKD in the lower extremity:

All tibiae to be radiographed utilizing 55KV

All femora to be radiographed utilizing 65KV

MilliAmpere Seconds (MAS): To achieve correct image density without compromising image contrast, MAS should serve as the **only** variable to compensate for differing part thickness and density. Suggestion: An adequate technique chart should be developed for the body part(s) to be imaged with consistent use of, and adherence to, the settings specified for the part thickness as determined by caliper measurement.

Processing Sensitometry: To achieve and maintain function of the processor, daily sensitometry must be performed and results recorded. Variations from normal must be corrected immediately.

Example Calculation Using X-Marker II

(Eisenlohr Technologies, Inc., Davis California) Radio-Opaque Ball:

A 30 mm radio-opaque ball is placed in the field of the X-ray at the approximate center of the X-ray. The diameter of the ball is measured from the X-ray. Since the diameter is known to be 30 mm, the following formula is used to calculate the magnification Conversion Factor (CF):

$$CF = 30\text{mm} \div \text{mm ball measurement from X-ray}$$

$$\text{Example: } 0.857 = 30 \text{ mm} \div 35 \text{ mm}$$

All length measurements made off this film would be multiplied by the 0.857 correction factor.

The determination of limb length discrepancy is calculated using the following formula, after all values have been corrected for magnification errors:

$$\text{Limb Length Discrepancy} = (d_2 - d_1) + \text{Lift} = \text{mm}$$

Where d is the distance from the top of the X-ray film to the top of the femoral head:

d1: contralateral side; d2: treated side

30 mm ball measures ____ mm on X-ray
 CF: $30 \div$ ball measurement = ____
 (Conversion Factor)

Limb Length Measurements
 (Note: Requires full-length standing AP views of the left and right limbs.)

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<u>Contralateral Limb</u>		<u>Treated Limb</u>	
Left <input type="checkbox"/>	Right <input type="checkbox"/>	Left <input type="checkbox"/>	Right <input type="checkbox"/>
$d_1:$	$\frac{\text{X-ray}}{\text{CF}} = \text{actual length}$ mm	$d_2:$	$\frac{\text{X-ray}}{\text{CF}} = \text{actual length}$ mm
$F_1:$	$\times =$ mm	$F_2:$	$\times =$ mm
$T_1:$	$\times =$ mm	$T_2:$	$\times =$ mm
		Lift:	mm

Using actual length:
 Limb Length Discrepancy = $(d_2 - d_1) + \text{Lift} =$ mm

d - distance from femoral head to top of x-ray
 F - Femur length
 T - Tibia length

Shown: measurement for limb length discrepancy due to short femur (left)

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Note: It is important that the limb length discrepancy estimation be accurate to within 0.5 cm.

Determination of Goal Length for This Procedure

After the total limb length discrepancy has been calculated, the goal of the lengthening procedure for this surgery must be determined. Generally, the maximum tolerated lengthening in a single procedure is about 80 mm, or 8 cm. Larger amounts cause the tissues to become too tight, and further lengthening then becomes extremely painful for the patient. If more than 80 mm is required, it would be advisable to separate the treatment into two procedures with at least 1 year between to allow the soft tissues time to adapt.

Less than 20 mm (2 cm) is generally considered easily managed by shoe lifts and not worth the surgical morbidity.

There are other factors to be considered prior to determining goal length.

- 1) Soft tissue viability: the skin should be intact without stretching or scarring; muscle tightness may result in contractures, and the effects on tendons, ligaments and blood vessels considered. Patient comfort as determined with block height should be a consideration.
- 2) The presence of joint fusions of hip or ankle: if the ankle is fused in 20 degrees of plantar flexion, the limb may need to be left 1 cm short to facilitate ambulation. A hip fusion might necessitate an extra 1-2 cm of lengthening in order for the limb to touch down.
- 3) Additional procedures which might be required to treat joint contractures should also be evaluated as to their effect on the ultimate length needed.

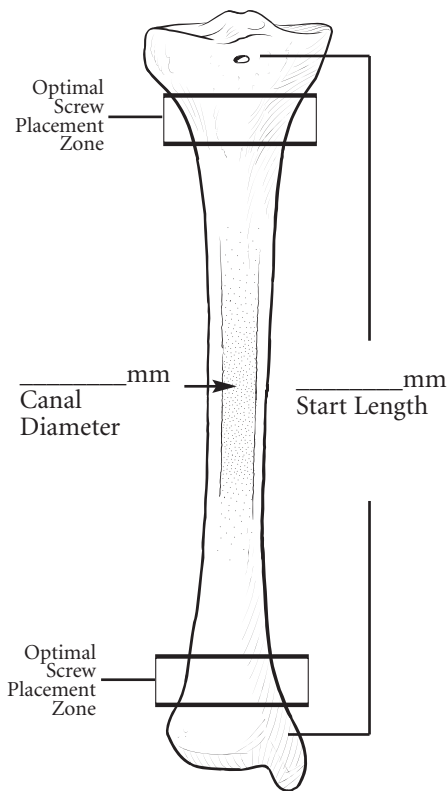


Figure 5

Lengthener Selection

After determining total limb length discrepancy and the goal length for this procedure, the correct size of ISKD must be selected. ISKD lengtheners are shipped according to the requirements specified for each surgical procedure, and a range of sizes will not be available in the operating room. Therefore, careful pre-operative planning is critical to the success of the procedure.

The ISKD is designed to lengthen a prescribed distance and then stop. ISKD lengtheners will distract a maximum of either 50 or 80 mm, depending on the model chosen. Thus the precise amount of lengthening required, the maximum starting length and fully distracted length of the ISKD must be determined prior to surgery in order to permit selection of the correct model of ISKD.

The ISKD is produced in a range of sizes that cover most indications. Following the instructions below will permit the surgeon to select the best model ISKD for the patient.

There are two considerations for choosing the correct lengthener model:

1. The lengthener must be dialed out or distracted by rotational movement to finish at the final goal length (Figure 6). For example: if goal length is 35 mm, the 50 mm lengthener must be extended 15 mm, or the 80 mm extended 45 mm, before insertion.
2. The ISKD starting length dialed out must fit within the dimensions of the bone, and should, therefore, be approximately 4 cm shorter than the total bone length.

Note: The selected ISKD does not have to match the maximum start length and ideal end length perfectly in order to achieve the correct amount of distraction and a successful result.

A shorter lengthener with more proximal distal locking can still produce successful results.

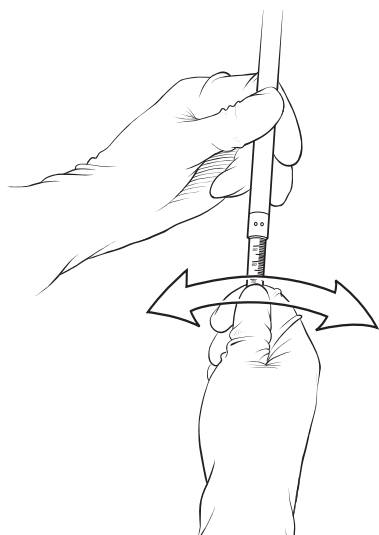


Figure 6

All ISKD implants are shipped in the non-distracted position and have calibration marks on the distal section. The ISKD must be “dialed out” to the appropriate start length prior to insertion by manipulating the lengthener mechanism to drive the distal section out of the proximal section, until the calibration mark for the amount of lengthening required is level with the distal end of the proximal section.

EQUIPMENT REQUIRED

Femoral Lengtheners

ISKD Diameter (mm)	Maximum Distraction (mm)	Start Length (mm)	Max. End Length (mm)	Catalog #
12.5	50	255	305	F12-255-305
12.5	50	300	350	F12-300-350
12.5	50	345	395	F12-345-395
12.5	80	255	335	F12-255-335
12.5	80	300	380	F12-300-380
12.5	80	345	425	F12-345-425
14.5	50	255	305	F14-255-305
14.5	50	300	350	F14-300-350
14.5	50	345	395	F14-345-395
14.5	80	255	335	F14-255-335
14.5	80	300	380	F14-300-380
14.5	80	345	425	F14-345-425

Packaged sterile

Tibial Lengtheners

ISKD Diameter (mm)	Maximum Distraction (mm)	Start Length (mm)	Max. End Length (mm)	Catalog #
10.7	50	215	265	T10-215-265
10.7	50	255	305	T10-255-305
10.7	50	300	350	T10-300-350
10.7	80	255	335	T10-255-335
12.5	50	215	265	T12-215-265
12.5	50	245	295	T12-245-295
12.5	50	255	305	T12-255-305
12.5	50	300	350	T12-300-350
12.5	80	255	335	T12-255-335
12.5	80	300	380	T12-300-380
13.5	50	215	265	T13-215-265
13.5	50	245	295	T13-245-295
13.5	50	255	305	T13-255-305
13.5	50	300	350	T13-300-350
13.5	80	255	335	T13-255-335
13.5	80	300	380	T13-300-380

Packaged sterile

ISKD Instrument Tray Kit

Part No.	Description	Quantity
10012	3 mm Allen Wrench	1
10017	6 mm Allen Wrench	1
11005	4.8 mm Drill Stop	2
1102101	Calibrated Drill Bit, 180 mm / 4.8 mm	1
1102701	Calibrated Drill Bit, 280 mm / 4.8 mm	1
1103001	Calibrated Drill Bit, 180 mm / 4.0 mm	1
17520	ISKD Femoral Nail Guide Bar	1
17525	External Jig Guide Bar	1
17350	3.5 mm Hexagonal T-Wrench	2
17351	Locking Screw Depth Gauge	1
17354	8 mm Straight Trocar	1
17355	6 mm T-Wrench w/U-Joint	1
17357	13 mm Spanner	1
17360	Screw Guide	3
17379	Guide Locking Screw	2
17391	Screw Adapter, Femur	1
17392	Sliding Hammer w/detachable swing arm	1
17410	Handle w/Bar Locking Screw, Tibial	1
17430	Locking Rod, Tibia	1
17440	Tibial Proximal Outrigger	1
17470	Pinted Awl	1
17491	Screw Adapter, Tibia	1
17510	Handle with Bar Locking Screw	1
17530	Locking Rod	1
17565	Drill Guide Ø 4.8 mm / 80 mm	1
170035	Black Handle w/Bayonet fitting	1

Tibial & Femoral Locking Screws

Shaft Diameter (mm)	Shaft Length (mm)	Catalog #
4.0	20	S4020
4.0	25	S4025
4.0	30	S4030
4.0	35	S4035
4.0	40	S4040
4.0	45	S4045
4.0	50	S4050
4.0	55	S4055
4.0	60	S4060
4.0	65	S4065
4.0	70	S4070
4.0	75	S4075
4.8	20	S4820
4.8	25	S4825
4.8	30	S4830
4.8	35	S4835
4.8	40	S4840
4.8	45	S4845
4.8	50	S4850
4.8	55	S4855
4.8	60	S4860
4.8	65	S4865
4.8	70	S4870
4.8	75	S4875

Tibial & Femoral Revision Locking Screws

Shaft Diameter (mm)	Shaft Length (mm)	Catalog #
4.0	20	RS4020
4.0	25	RS4025
4.0	30	RS4030
4.0	35	RS4035
4.0	40	RS4040
4.0	45	RS4045
4.0	50	RS4050
4.0	55	RS4055
4.0	60	RS4060
4.0	65	RS4065
4.0	70	RS4070
4.0	75	RS4075
4.8	20	RS4820
4.8	25	RS4825
4.8	30	RS4830
4.8	35	RS4835
4.8	40	RS4840
4.8	45	RS4845
4.8	50	RS4850
4.8	55	RS4855
4.8	60	RS4860
4.8	65	RS4865
4.8	70	RS4870
4.8	75	RS4875

Supplemental Equipment

Part No.	Description
FTM2000	ISKD Monitor
650179	Physician Manual w/Software

Equipment Cleaning and Maintenance

The instrumentation should be cleaned thoroughly using medical grade alcohol 70% + distilled water 30%.

Detergents with free fluoride, chloride, bromide, iodide or hydroxyl ions must not be used, as they will damage the black anodized coating on any Orthofix products.

After cleaning, the instruments should be rinsed with sterile distilled water and dried using clean non-woven fabric. **The nail support handle (17410) should not be dismantled**, but should be cleaned and sterilized as one piece. The **sliding hammer (17392)** comes apart for cleaning: the wing nut on the end of the bar has a reverse thread, and should be turned clockwise to remove it. The hammer can then be slid off, and the central lumen can be cleaned. The hammer should then be reassembled before sterilization. Particular attention should be paid to cleaning the threaded hole at the end of the **locking rod (17430)**, and the holes in the **guide bar (17420)**.

Sterilization

The ISKD lengtheners are provided in sterile packaging. Locking screws are provided in sterile packaging except in the U.S. Prior to surgical use, the instrumentation and non-sterile screws should be cleaned as described above and sterilized by steam autoclaving following a validated sterilization procedure, utilizing a prevacuum cycle. Orthofix recommends the following cycle: steam autoclave 132° – 135° C [270° – 275° F], exposure time 10 minutes.

Note: THE LENGTHENERS, END CAPS AND BONE LOCKING SCREWS SHOULD NEVER BE REUSED.

These implants may look “as new” when removed, but will have been subjected to considerable stresses while in the patient and their fatigue life is not sufficient for second usage. No attempt should be made to shorten the ISKD implants so that they can be re-used.

Bibliography

- 1) Paley, Dror, Herzenberg, J.E., Tetsworth, K., McKie, J., and A. Bhav. Deformity Planning for Frontal and Sagittal Plane Corrective Osteotomies. Orthopaedic Clinics of North America. 25:3, 1994
- 2) Cole, J. Dean, et al. “The intramedullary skeletal kinetic distractor (ISKD): first clinical results of a new intramedullary nail for lengthening of the femur and tibia.” Injury, Int. J. Care Injured 32 (2001): 129-139.
- 3) Paley, Dror, and J.E. Herzenberg. Principles of Deformity Correction. Springer, 2001.

Patient Preparation and Positioning

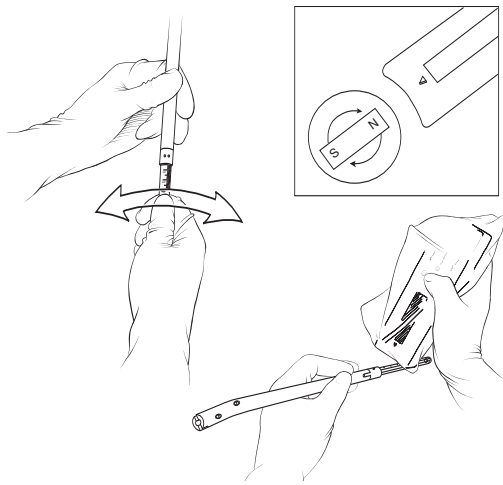
The patient is placed supine on an operating table or osteotomy table, either with the knee flexed and the affected leg hanging vertically down, or with the knee flexed over a padded bar, taking care to avoid any pressure on the fibular head (common peroneal nerve). Patient positioning for the ISKD procedure is the same as that for nailing procedures. The leg is then cleaned and sterilized from mid-thigh to toes, and draped separately. Fluoroscopic visualization of the entire tibia is essential and should be confirmed prior to sterilization and draping of the lower extremity in the standard manner.

Functional Check

Prior to inserting the ISKD, and under sterile conditions, its length should be set to the amount determined during preoperative planning. This is done with small back-and-forth rotations of the distal section relative to the proximal. **Note: the device should not be distracted too far.**

The ISKD only advances when the sections are rotated and therefore cannot be shortened.

The integrity of the magnet that is used to monitor the progress of ISKD lengthening after surgery should be checked using an ISKD monitor that has been placed in a double sterile bag. The monitor is turned on, allowed to reset and then placed just above the Key ring at the distal end of the proximal section. The entire lengthener should then be rotated slowly until the monitor signals two changes in polarity. The two points of change in polarity should be approximately 180° apart on the lengthener. If there are more than 2 changes in polarity during a single 360° rotation, if there does not appear to be any change in polarity, or if the changes in polarity occur less than 180° apart, the magnet may be damaged and a different ISKD should be used. See ISKD monitor manual for operating instructions.





Venting of the Intramedullary Canal

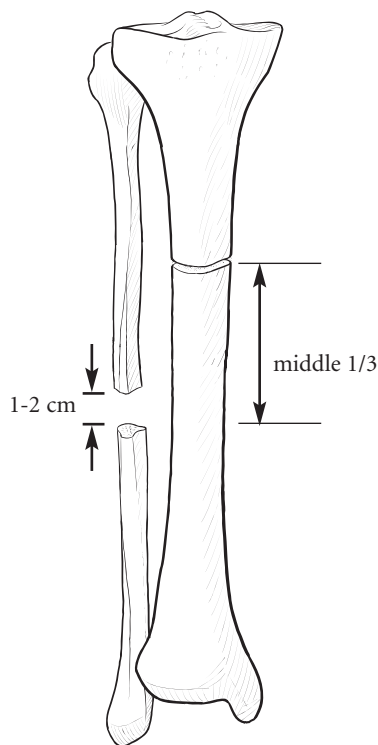
Insertion of the ISKD is a form of closed tibial nailing, a procedure that has been associated with the generation of high intramedullary pressures during reaming and nail insertion that has the potential to induce compartment syndrome or fat embolism. For this reason, vent holes should be prepared in the tibia to provide a means for reduction of intramedullary pressure prior to reaming and/or lengthener insertion.

Venting consists of drilling one or two 6 mm diameter holes in the distal tibia across one cortex and into the intramedullary canal. Position the vent below the most distal end of the ISKD when inserted.

A hollow cannula is inserted into the hole so that the tip of the cannula is flush with the intramedullary cortical surface. The cannula should not protrude into the intramedullary canal as it may interfere with intramedullary reaming. Uninterrupted flow of intramedullary contents from the cannula should be confirmed frequently during the procedure by clearing the cannula with a guide wire. The venting cannula should be removed after the ISKD has been inserted and prior to distal locking.

Osteotomy

An osteotomy is created at the junction of the upper and middle 1/3 of the tibia. This position provides maximum stability of the ISKD and optimal biomechanical conditions for activation of the lengthening mechanism. Under ideal conditions, the osteotomy site is positioned so that as distraction occurs the growing regenerate will be supported by the wider proximal section of the lengthener rather than by the smaller distal section. It is recommended that the osteotomy site be placed superiorly to the transition point of the proximal and distal section of the device, at a distance at least 3 cm more than the intended distraction.



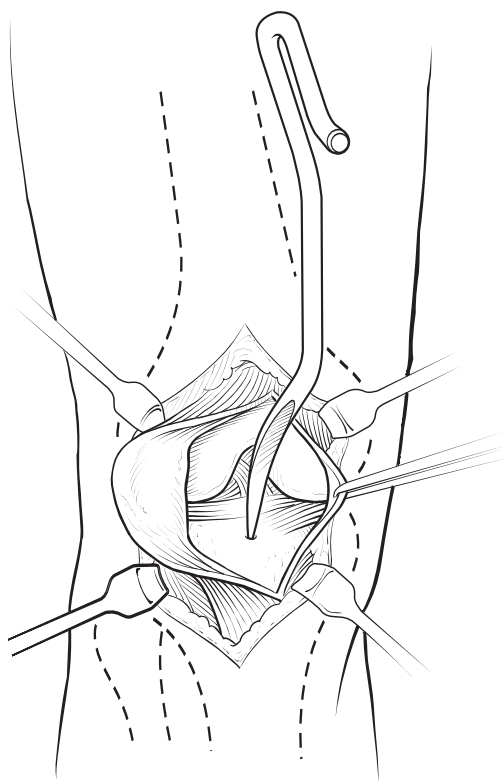
Under no circumstances should the osteotomy be performed in the proximal or distal metaphyseal areas where the larger intramedullary canal diameter may lead to instability of the distraction fragment, and the resulting higher bending moments will result in excessive loading of the ISKD.

The osteotomy can be performed either with an intramedullary saw or with an osteotome through a small incision. When using either method, it is important to preserve the periosteum to protect the blood supply to the regenerate bone. A periosteal elevator used to separate the periosteum from the bone will decrease the possibility of periosteal damage. The osteotomy can also be performed by drilling a series of small holes in the bone and connecting the holes with an osteotome. The osteotomy should be smooth and transverse to allow easy rotation. As it is imperative that the two bone segments rotate freely and independently of each other, it is important to perform a rotation test after the osteotomies are complete.

An osteotomy of the fibula must also be performed. Because the fibula regenerates much faster than the tibia, a 2 cm section of bone should be removed from the fibula in the lower middle 1/3 of the bone. A distal syndesmosis screw is essential to stabilize the fibula at the ankle joint. Proximal stabilization may also be performed through the fibular head, avoiding the neck, but is often not necessary.

Insertion Site

This procedure is crucial to the success of the operation and adequate time should be taken to ensure the correct positioning of the entry portal before proceeding to the next stage.



A 5 cm vertical skin incision is made in the midline, centered at the level of the tibial plateau, and extended down to the deep fascia. The skin and subcutaneous tissues are reflected medially until the medial border of the patellar tendon is visible. An incision is then made medial to the tendon, proximal to the tibial tuberosity. The tendon is retracted laterally, and the midpoint of the anterior margin of the tibial plateau identified.

Because the lengthener is relatively rigid, an anterior entry portal must be very proximal, no more than 1 cm distal to the anterior edge of the tibial plateau. A more distal entry point may result in damage to the posterior cortex during insertion of the implant.

The awl, or a cannulated cutter over a guide wire or Steinmann Pin, is used to open the medullary canal in the midline, taking care to keep the straight part of the shaft of the awl parallel to the long axis of the tibial shaft. An early check should be made with the Image Intensifier in both the sagittal and frontal planes to confirm that the tip of the awl or guide pin is in line with the tibial canal. It is more difficult to alter the entry portal once it has been fully established.

A 7 mm Rigid Reamer should be used to reach the medullary canal, and to confirm alignment. A Large Rigid Reamer should be used to enlarge the metaphyseal entry portal to 9 mm, but they should not be used to ream cortical bone. Flexible power reamers will be used to ream the diaphysis.

Throughout this procedure, care should be taken to retract the patellar tendon away from the operating field. Utilizing a self-retaining retractor and the tissue protector will assist in avoiding bruising of the articular surface of the patella, or the overlying skin.

Guide Wire Insertion

A guide wire is inserted through the entry portal and passed through the proximal fragment. Once the proximal side of the osteotomy site has been reached, the guide wire is manipulated in such a way that it reaches the distal fragment. In difficult cases, it is useful to clamp a T-handle to the proximal end of the wire for additional control. Guide wire insertion must be carried out under image intensification in two planes. In a mid-shaft osteotomy, 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.

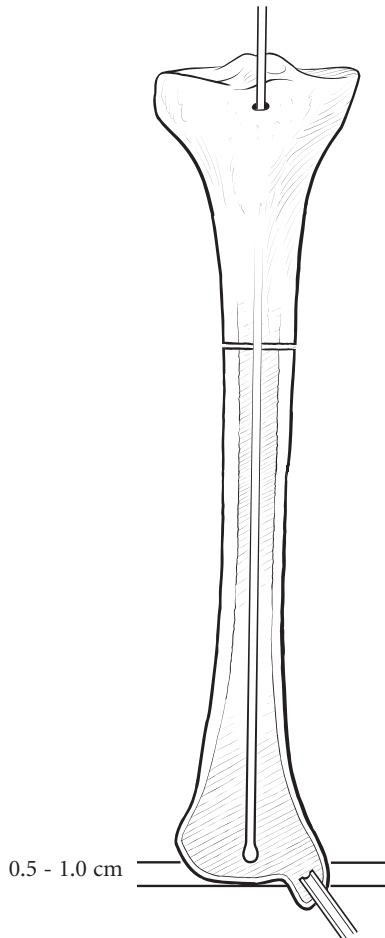
The guide wire is inserted until its tip sits 0.5–1 cm proximal to the ankle joint, care being taken to ensure that it is exactly in the midline. It must be remembered that the reamer will follow the guide wire, and that the lengthener will follow the same track. If the tip of the wire is positioned too far medially, the end of the lengthener will, in turn, be medial, and a valgus deformity will result. Similarly, if the tip of the wire is positioned too laterally, a varus deformity will result. Another important reason for the central positioning of the guide wire is that an eccentric wire may result in asymmetrical reaming, with a disproportionate amount of the cortex being removed on one side.

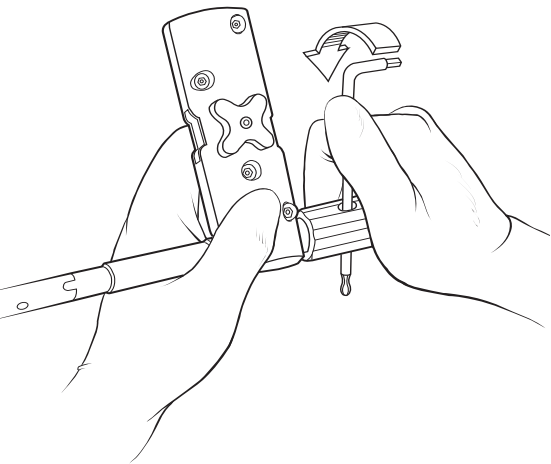
Reaming

The medullary canal is now reamed by passing the reamer over the guide wire, always starting with a 9 mm reamer. Reaming should then be continued in 0.5 mm increments, up to a width 1.5–2.0 mm greater than the lengthener diameter. A soft tissue protector should be used proximally. Reaming past the isthmus is necessary as it is important that the ISKD does not fit too tightly in the intramedullary canal, and to permit easy rotational movement of the wider proximal section in the distal fragment, which is required for good function of the lengthening mechanism. Steady pressure should be exerted while reaming slowly, 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, 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, in increments of only 0.5 mm. A reamer that is not advancing for any reason may cause significant thermal damage to bone and soft tissues. Avoid turning off power while the reamer is in the canal, as this may cause the reamer to jam.

The guide wire may slip back a little when the reamer is withdrawn. This problem may be eliminated if the guide wire is lightly tapped prior to reaming, to embed it in the hard cancellous bone above the tibial plafond. It should also be kept in this position by gentle pressure at the proximal end during withdrawal of the reamer. Finally, when reaming is complete, the guide wire should be removed, and the incision should be irrigated with normal saline to ensure the removal of all fragments of bone, to help prevent heterotopic ossification, which may be one of the causes of post-operative knee tenderness.





Lengthener Insertion

The ISKD end cap is first removed from the lengthener using a 3.5 mm T wrench.

The end cap must be replaced after lengthener insertion.

The Locking Rod is inserted into the back of the Handle and the chosen lengthener into the lengthener support. The handle should be oriented such that its length points in the direction of the lengthener bend. The lengthener must be rotated until it seats into the correct position, and the locking rod is then firmly tightened into the lengthener, completing this with the 4 mm Allen Wrench.

Before the lengthener is inserted, it is important to check alignment of the proximal holes in the lengthener and the guide bar. In order to do this, the guide bar is mounted on to the handle following the procedures described under “Proximal Locking”.

The lengthener is now manually inserted, under image intensification with the handle pointing anteriorly. The lengthener is advanced until the step on the lengthener support is flush with the surface of the bone. This indicates that the lengthener has been inserted to the correct depth. Ideally, the lengthener should be inserted by hand, but gentle tapping may be necessary.

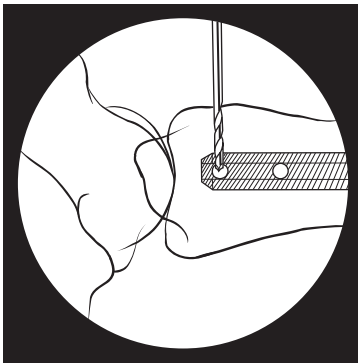
Under no circumstances should insertion of the ISKD require vigorous hammering. If the ISKD does not advance easily, it should be removed and additional reaming performed.

Distal Locking

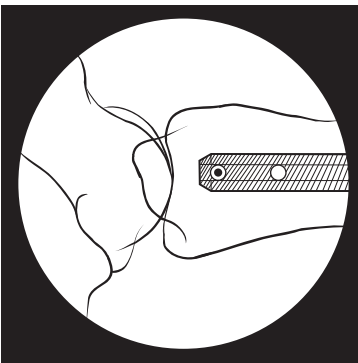
Distal locking of the ISKD must be performed using a freehand technique, preferably with a radiolucent drill.

1. A lateral image is obtained so that the locking holes are seen as true circles.
2. The correct position for the skin incisions is located with the skin marker from the Image Intensifier. Stab wounds are made past the deep fascia, and the bone exposed by blunt dissection.
3. The tip of the drill bit is positioned on the bone in the center of the circle as viewed on the fluoroscope.
4. The drill bit is orientated so that it appears as a small dot on the fluoroscope in the center of the circle.
5. The drill bit is then advanced through both cortices and the locking screw inserted.

Step 1



Step 2

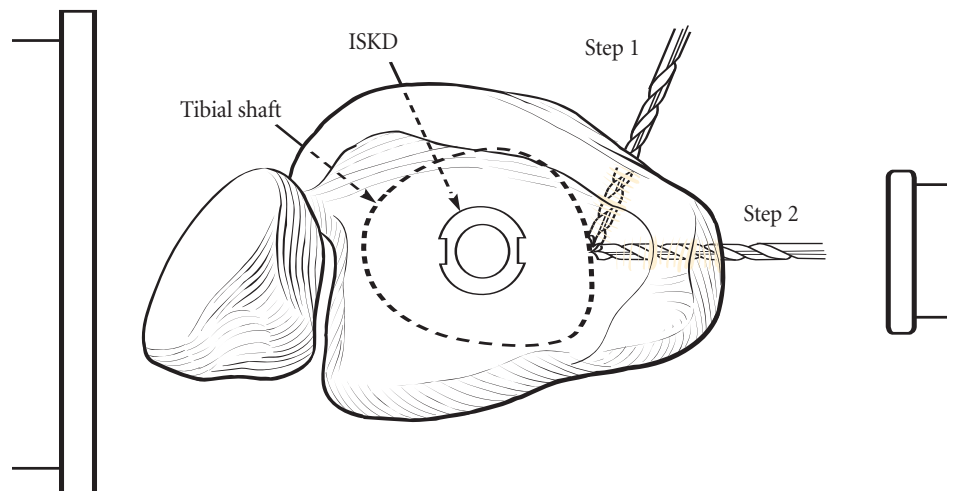


Possible variations of the technique:

A) A 4.0 mm drill bit can be used initially to gain access more easily through the locking holes in the nail. However, it is essential to open the hole out to 4.8 mm before inserting the locking screw.

B) A 2.0 mm Kirschner wire can be used for the initial targeting to penetrate the lengthener. When the wire is in the correct position, a cannulated 4.8 mm drill bit can be used over it to drill the hole.

It is very important that two proximal and two distal locking screws are used for biomechanical stability.



Proximal Locking

Prior to proximal locking, perform a test of the osteotomy site with the Image Intensifier to assure that the intended gap space of approximately 2.0 mm is present to optimize rotation. It may be necessary to impact the proximal lengthener to ensure that the appropriate gap is present. As it is imperative that the two bone segments can rotate freely and independently of each other, it is important to check for this gap before proximal locking.

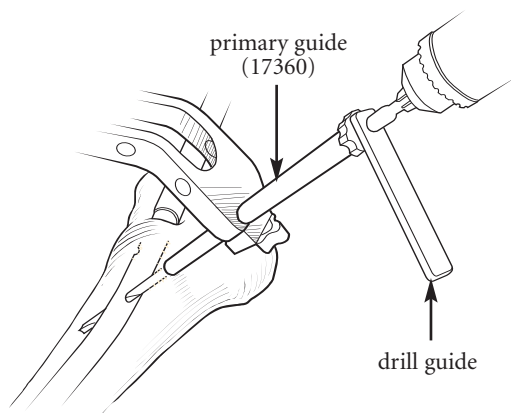
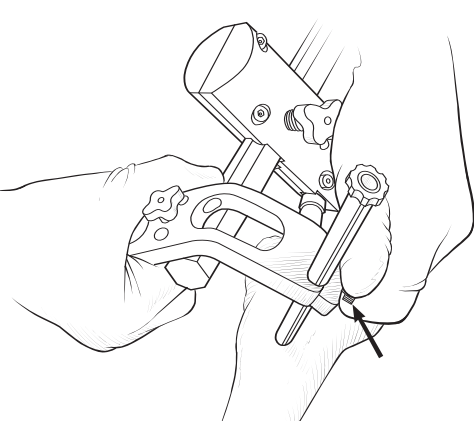
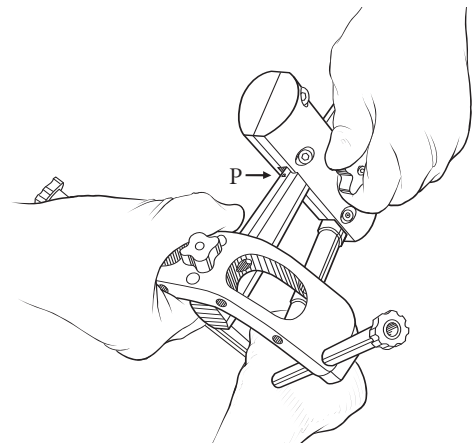
The guide bar locking screw is loosened, and the bar moved until the P mark is level with the front surface of the handle, where it is locked into position. The proximal outrigger is mounted on the bar, and two primary screw guides (17360) are inserted into the guide seats of the outrigger to locate the sites for the incisions. 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.

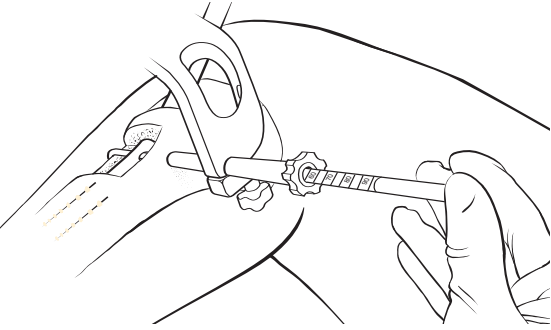
An intermediate screw guide (11124) is inserted into each screw guide, followed by a 4.8 mm drill guide on the medial side. The 4.8mm drill bit is introduced down to the bone, and pressed against the cortex to fix the tip before drilling.

The surgeon drills steadily through the first cortex. The drill should be stopped when the second cortex is reached. The drill stop is moved down until it is about 10 mm above the top of the drill guide, and locked into place. This represents the thickness of the second cortex. Drilling is now continued through the second cortex. The drill stop prevents damage to the tissues beyond the bone, and also provides an alternative method of estimating the correct length of the locking screw.

The drill bit is removed, along with the drill guide and intermediate screw guide.

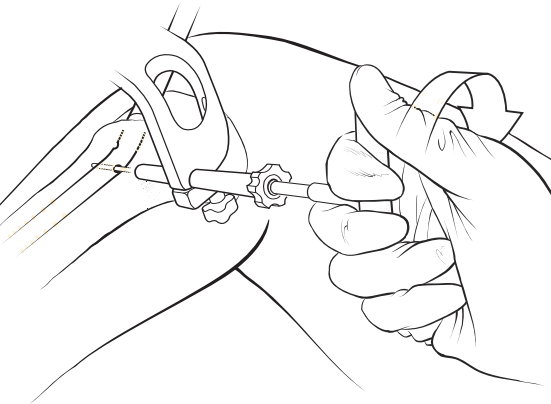
Do not drill the second hole before inserting the first locking screw.





An appropriate length locking screw is determined using the Locking Screw Depth Gauge as follows: the surgeon should first check that the primary 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 can now be read at the top of the screw guide. This depth gauge is only suitable for use with Orthofix ISKD Tibial and Femoral Lengtheners, since its accuracy depends on the fixed length of the primary screw guide.

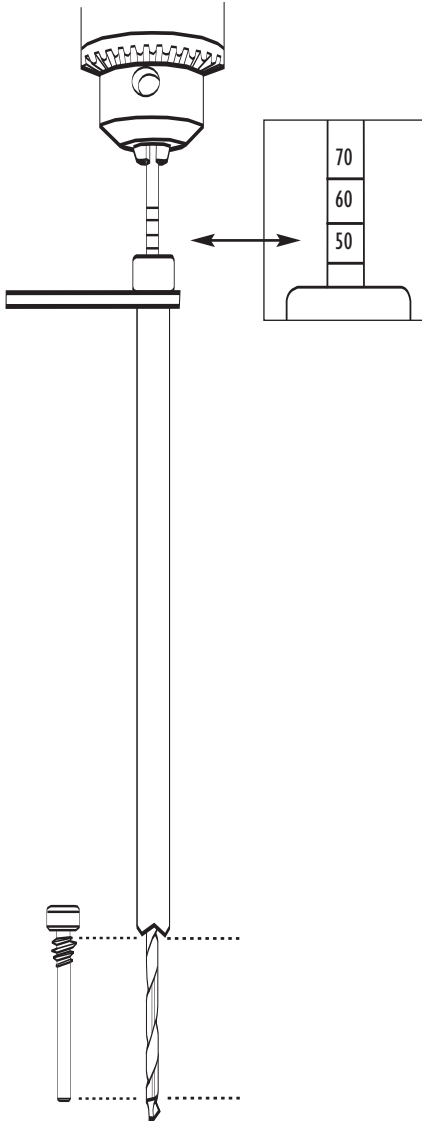


A locking screw of correct length is now inserted into the proximal screw guide, and pushed through the bone with the Screw T-wrench, until its thread engages the medial cortex. Note that there is a circular mark on the T-wrench. This mark will be 7-12 mm above the top of the primary screw guide when the locking screw has been pushed in sufficiently, depending on the length of the thread on the locking screw. Turning the T-wrench until this position has been reached is ineffectual because there will be no thread in contact with the bone.

The T-wrench is now turned steadily clockwise, exerting gentle pressure, until the mark on the shaft of the T-wrench reaches the top of the screw guide. One more full turn should be made to tighten the screw fully. **It is important not to continue turning after this position has been reached, or the thread in the bone will be stripped. Should this happen, the screw should be removed and a Revision Locking Screw inserted, which has a wider thread. Alternatively, the screw should be inserted from the opposite direction as the threads in the screws are only proximal and the opposite cortex will not be stripped.**

The second locking hole is now drilled, using an identical technique. The length of the second locking screw is determined as described above, and the same technique followed for insertion of the second locking screw. Both screw guides are now removed by loosening the guide locking screws.

While in the O.R., perform a limb rotation test to assure easy rotation.



Alternative Methods of Estimating the Locking Screw Length

1. Using the drill guide assembly, reference the calibration on the drill bit before drilling and subtract it from the reference calibration after the drill bit has penetrated the far cortex of the bone.

2. Alternatively, the appropriate locking screw length, from the base of the screw head to its tip, can be determined by measuring the amount of drill bit protruding from the screw guide utilizing the drill stop and drill guide assembly. *A metal ruler is not provided in the instrumentation, however, any ruler with a centimeter scale may be used. The tapered tip of the drill bit should be ignored in this measurement.*

Removal of the Jig Assembly and Closure

The proximal outrigger 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 4 mm Allen wrench.

The Lengthener End Cap provided with the device is screwed into the end of the lengthener, then locked into place with the T-wrench. Closed suction drainage is advised for the insertion wound. After final careful irrigation to remove any remaining bone fragments, the incision should be sutured in layers in the usual fashion. Firm dressings should be applied to prevent hematoma formation. The drainage is removed after 24-48 hours.

Weight Bearing

The patient may be mobilized on day 1 or 2, after drainage has been removed, but all weight bearing should be avoided. Partial weight bearing (50 lbs. / 22.7kg) with crutches may be initiated after one week or upon doctor's permission and continued throughout the lengthening and consolidation process. Weight bearing may be increased to full body weight as soon as cortication of the regenerate is evident in 3 of 4 cortices during the end of the consolidation phase.

Isometric muscle exercises for the whole limb should be encouraged from the outset. Gentle knee mobilization may be started after about four days, within the limits of comfort. Normally, a good range of knee and hip movement is achieved spontaneously. Too vigorous a program of physiotherapy may be harmful and should only be undertaken under specific order of the physician.

Control of the Lengthening Process

The ISKD is designed to lengthen under physiological movement. In general, the activities of everyday life combined with controlled ambulation and partial weight bearing will produce lengthening. For the patient, the primary tool to determine distraction rate is the ISKD monitor, which must be used frequently each day during distraction. It is necessary for the patient to be educated on the use of the monitor prior to surgery. (For more detailed information concerning use of the monitor, refer to the Orthofix ISKD Magnetic Sensor Instruction Manual). By varying activity levels, the patient should be able to control the rate of lengthening accurately to that prescribed by the physician. During the distraction phase, the surgeon's office should contact the patient on a daily basis to confirm lengthening activity and monitoring compliance.

Lengthening activity should be initiated by day 5 post-operatively for the tibia and by day 3 for the femur, as the femur tends to consolidate faster. The progress of lengthening and the efficacy of the monitor should be checked regularly against follow-up radiographic evidence of the rate of lengthening and the quality of the regenerate. While 1 mm per day is generally recommended, clinical and radiographic examination may show that lengthening should progress at a faster or slower pace. Starting week one post-operatively, it is recommended to schedule radiographic exams every two weeks on average during the distraction phase. More or less frequent examination should be considered based on patient progress.

Note: Monitor function is limited to 2 inches (5 cm) distance from the ISKD lengthener magnet. If this distance is greater than 2 inches (55 mm) more frequent radiographs may be required to check the lengthening progress.

In cases where normal ambulation does not produce adequate lengthening, gentle manipulation of the affected limb can be performed by the patient while frequently checking the progress of lengthening with the monitor. In some instances, it may be advisable for a family member or other individual to assist the patient with their daily exercises.

Consolidation Phase

The Consolidation Phase starts when distraction is complete. During this phase, the regenerate that was made at the osteotomy site must harden into bone. Patients should be monitored at one month and then quarterly until all four cortices of the bone are complete. Consolidation is evaluated through radiographs. Weight bearing may be increased to full body weight as soon as cortication of the regenerate is evident in three of four cortices.

Consolidation should occur with the ISKD in place. It should not be removed until full consolidation has occurred. Should hardware problems develop, such as screw breakage or backout, or nail bending, the ISKD should be replaced with an IM nail.

Lengthener Removal

ISKD removal may normally be carried out after 12-18 months provided there is radiological evidence of consolidation.

The proximal end of the ISKD is exposed through a small incision. It may be necessary to clear some new bone from the end of the lengthener. The end cap is removed with the T-wrench, and the Screw Adapter screwed into the end of the ISKD, and tightened firmly by hand. This should be accomplished prior to the removal of the proximal locking screws to prevent the ISKD from deflecting posteriorly.

Once all locking screws have been removed, the lengthener is removed either by manual traction on the screw adapter, or if hammering is required, by attaching the sliding hammer to its proximal end. The wound is closed and dressed in the normal manner.

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