INTRODUCTION

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 through distraction osteogenesis, as a result of deliberate, rotational limb movement of between 3° and 9° at the knee. Accurate pre-operative planning is a requirement to determine leg length discrepancy and ultimate goal length of the procedure.

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The recommendations in this surgical technique should serve as a guide for the use of the ISKD. Each surgeon should evaluate the appropriateness of the technique based upon their judgment and technical expertise.

PATIENT SELECTION

Patient selection is critical to the success of the ISKD result, based upon the following:

- The patient must be able to achieve 3° - 9° rotation at the osteotomy for distraction to occur.
- Patient must not weight bear more than 50 lbs (22 Kg) via toe touch through the bone consolidation phase.
- 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 new bone formation quality.
- Patients who are unable or unwilling to comply with the post-operative distraction instructions are poor ISKD candidates.
- The ISKD lengthener has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. The ISKD lengthener has not been tested for heating or migration in the MR environment.
- Patients should have a supportive home environment and assistance with lengthening exercises. This could be a significant contributor to a successful outcome.
MEASUREMENT OF LIMB LENGTH DISCREPANCY

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

THE CLINICAL TECHNIQUE

The clinical examination should be conducted first. The patient stands 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 (Fig. 1). Ensure that both knees are in the same amount of extension. The foot should be positioned so that each patella points forward. This may require rotation of the foot (Fig. 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 5mm 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 (Fig 4).

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, 4 are from: Paley, D., Herzenberg, J.E., Tetsworth, K., McKie, J., Bhave, A. Deformity Planning for Frontal and Sagittal Plane Corrective Osteotomies. Orthopaedic Clinics of North America, 25:3, 1994
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. (Fig. 3)

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

- 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.

- Scanograms may be less useful because some are taken with the patient non-weight bearing 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. Any ball or scale used to estimate magnification must be at the same distance from the X-ray film cassette as the bone.

All determinations of limb length discrepancy using the radiographic technique must account for magnification errors.
PROCEDURE (Fig. 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
   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 body 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 ISKD femoral procedures, all femora to be radiographed
utilizing 55KV.

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.
PRE-OPERATIVE PLANNING

EXAMPLE CALCULATION USING X-MARKER II

(Eisenlohr Technologies, Inc., Davis California)

Radio-Opaque Ball:
A 30mm radio-opaque ball is placed approximately in the center of the X-ray field. The diameter of the ball is measured from the X-ray. Since the diameter is known to be 30mm, the following formula is used to calculate the magnification:

Conversion Factor (CF)
CF = 30mm ÷ ___mm ball measurement from X-ray
Example: 0.857 = 30mm ÷ 35mm
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:

Limb Length Discrepancy = (d2 – d1) + Lift = _____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

NOTE: It is important that the limb length discrepancy estimation be accurate to within 5mm.

30mm ball measures _____mm on X-ray
CF: 30 ÷ ball measurement = _______ (Conversion Factor)

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

<table>
<thead>
<tr>
<th>Contralateral Limb</th>
<th>Treated Limb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left □</td>
<td>Right □</td>
</tr>
<tr>
<td>d1: ( \frac{X-ray}{CF} \times \text{actual length} ) mm</td>
<td>d2: ( \frac{X-ray}{CF} \times \text{actual length} ) mm</td>
</tr>
<tr>
<td>F1: ( \frac{X-ray}{CF} \times \text{actual length} ) mm</td>
<td>F2: ( \frac{X-ray}{CF} \times \text{actual length} ) mm</td>
</tr>
<tr>
<td>T1: ( \frac{X-ray}{CF} \times \text{actual length} ) mm</td>
<td>T2: ( \frac{X-ray}{CF} \times \text{actual length} ) mm</td>
</tr>
<tr>
<td>Lift: ( \frac{X-ray}{CF} \times \text{actual length} ) mm</td>
<td></td>
</tr>
</tbody>
</table>

Using actual length:
Limb Length Discrepancy = (d2 - d1) + Lift = _____mm

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

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PRE-OPERATIVE DETERMINATION OF FEMORAL LENGTHENING GOAL

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 80mm. Larger amounts may cause the tissues to become too tight and further lengthening then becomes painful for the patient. It would be advisable to separate the treatment into two procedures with an adequate time interval to allow soft tissue adaptation.

There are other factors to be considered prior to determining the lengthening goal:
• 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 must be considered. Patient comfort during block height measurement could be an indicator of tissue tightness.
• 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 10mm short to facilitate ambulation. A hip fusion might necessitate an extra 10-20mm of lengthening in order for the limb to touch down.
• Additional procedures which might be required to treat joint contractures should also be evaluated as to their effect on the ultimate length needed.
LENGTHENER SELECTION

Careful pre-operative planning to determine the correct ISKD lengthener size is critical to the success of the procedure. After determining total limb length discrepancy and the goal length for this procedure, the correct ISKD lengthener size must be selected.

The ISKD is designed to lengthen a prescribed distance and then stop. ISKD lengtheners will distract a maximum of either 50 or 80mm, 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 (Fig. 5).

The ISKD is produced in a range of sizes for limb lengthening.

There are four considerations for choosing the correct lengthener model:

• The lengthener must be predistracted by rotational movement to the planned start length (Fig. 6). For example: if goal length is 35mm, the 50mm lengthener must be predistracted 15mm, or the 80mm predistracted 45mm, before insertion.

• The ISKD predistracted starting length must fit within the dimensions of the bone, and should, therefore, be approximately 40mm shorter than the total bone length.

• The most narrow canal diameter should be used to select the correct ISKD diameter. Additional reaming up to 2mm is recommended (see reaming, page 12). The diameter of the device should be 8mm less than the minimum diameter of the femur, to allow for a minimum of 3mm of circumferential bone after reaming and 2mm of over-reaming.

• It is suggested that the lengthener size be verified using a lateral view of the femur so that the anterior bow of the individual patient anatomy is considered.

For the ISKD to pass with only gentle pressure, and to avoid the need for excessive reaming, the osteotomy should be situated close to the position where the anterior bow is maximal in the lateral view (The implant is straight and will not therefore pass down a curved bone).

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. Use of a shorter lengthener with more proximal distal locking can still produce successful results.

If the shape of the bone dictates a more proximal osteotomy, a shorter implant should be chosen, so that an ideal length of the ISKD is distal to the osteotomy (see also page 10 and Fig 10).

The lengthener of choice should ideally be implantable at 40mm less than the initial length of the Intermedullary canal. An ISKD lengthener can be used to manipulate friction between the endosteal canal and lengthener. The more cortical contact will result in greater friction and increased effort for distraction, but if there is too little cortical contact, lengthening may be too rapid.
PATIENT PREPARATION AND POSITIONING

Position the patient in either the supine or lateral decubitus position, as determined by surgeon preference. The image intensifier should have free access to the entire femur in both planes. Patient positioning for the ISKD procedure is the same as that for nailing procedures. The leg is shaved from the anterior superior iliac spine to the proximal tibia. After the skin has been prepared, the leg is draped so that the femur is completely accessible from the region of the anterior superior iliac spine to the distal end of the condyles, with about 150mm of exposed skin visible proximal to the tip of the greater trochanter. The use of a transparent adhesive skin drape around the exposed skin, centered on the lateral side, is recommended.

PRELIMINARY SETUP

Prior to inserting the ISKD, and under sterile conditions, 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 (Fig. 7).

NOTE: The device should not be distracted too far. The ISKD only advances when the sections are rotated and therefore cannot be shortened.
VENTING OF THE INTRAMEDULLARY CANAL

Insertion of the ISKD is a form of closed femoral 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 femoral to provide a means for reduction of intramedullary pressure prior to reaming and/or lengthener insertion.

Venting consists of drilling one or two 6mm diameter holes in the distal femur across one cortex and into the intramedullary canal. Position the vent so it lies 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 (Fig. 8). 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.

Note: an alternative technique, based on surgical preference, utilizes the osteotomy site for venting in lieu of a distal cannula, with the intention to promote prophylactic bone grafting. This is achieved if the surgeon drills holes at the osteotomy site before reaming, completing it with a sharp osteotome just before implant insertion. The use of this technique makes reaming easier because the bone remains structurally intact, and the drill holes allow the medullary canal to decompress during reaming, so it is not necessary to complete the osteotomy until after reaming is complete.
**OSTEOTOMY**

Prior to the osteotomy it is advisable to set torsion correction markers in order to keep rotational stability and avoid a dislocation of the fragments. This could be either a K-wire or a long screw.

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 30mm more than the intended distraction. (Fig.9) For example, in a lengthening of 35mm, the osteotomy must be at least 65mm proximal to the distal end of the thick section of the ISKD. The osteotomy position can be more proximal than this, to suit the anatomy of the bone, but should never be more distal. The most proximal position advised is 30mm distal to the most distal of the proximal locking screws.

**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 produce excessive loading of the ISKD.**

The osteotomy can be performed with an osteotome through a small incision. When using this 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 posterior cortex may be difficult to cut and may be broken through osteoclasis by rotating the limb. The osteotomy should be smooth and transverse to allow easy rotation. It is imperative that the two bone segments can rotate freely and independently of each other, a rotation test should be performed.

In summary, the position of the osteotomy will be dictated in part by the shape of the bone in the lateral view. It is important to adjust the length of the ISKD to be used so that the above parameters are complied with, and that there are 30 to 50mm of the thicker part of the ISKD remaining in the distal bone fragment when lengthening is complete. Too little bone may result in excessively fast lengthening with increased pain and poor regenerate formation, whereas too much bone may cause increased resistance to the torsional movements necessary for lengthening, with a risk of premature fusion of the osteotomy.
INSERTION SITE

The insertion 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 7-10mm incision proximal to the greater trochanter is required. Haemostasis should be carried out once the iliotibial band has been reached. The tip of the greater trochanter is palpated, and the fibers of the iliotibial band divided exactly in the middle of the trochanter.

The dimensions of the trochanter should be checked by palpation, to locate the insertion point in the mid-line. The precise point of insertion is most important, and the ideal position is in the piriform fossa, close to its lateral wall, just medial to the greater trochanter. (Fig.10a)

Note: The point of insertion should never be too medial, in order to avoid injury to the Circumflex Femoral Artery.

It is advisable to expose the greater trochanter if there is any uncertainty, and a clear visualization is important to ensure the correct portal of entry.

Using a K-wire and cannulated reamer, create an entry to the piriform fossa just medial to the trochanter. Once the point of the reamer has been inserted 10-20mm, a check should be made with the image intensifier.

It is vital that the tip of the reamer is directly in line with the axis of the diaphysis in both planes, and that the final insertion point is governed by the alignment of the awl with the medullary canal, and not only by anatomical landmarks.

If necessary, the reamer is moved until the alignment is correct. It is then inserted into the femur along the axis of the bone for 30-40mm, keeping the straight part of the handle in line with the diaphysis, and using pressure with rotational movements. Particularly in younger patients where the bone is harder, it may be necessary to extend the entry portal through the metaphysis with Rigid Reamers.

The entry portal must be in the correct position as too lateral or too medial a position may cause difficulties with impingement of the lengthener on the opposite cortex. (Fig.10b) In all cases, a careful check of the alignment with the image intensifier is strongly recommended.
GUIDE WIRE INSERTION

A guide wire is inserted through the entry portal and passed though 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 guide 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 guidewire is dictated by the contour of the medullary canal, and this may help to prevent valgus or varus displacement of the distal fragment.

It must be remembered that the reamer will follow the guide wire, and the lengthener will then follow the same track. If the tip of the wire is positioned too far medially in the medial condyle, the end of the lengthener will be sited in the medial condyle, and a valgus deformity will result. Similarly, if the tip of the wire is too far over in the lateral condyle, a varus deformity will result. Another important reason for the guide wire being central is that an eccentric wire may result in asymmetric reaming, with a disproportionate amount of the cortex being removed on one side.

The guide wire will be central if it is driven down until its tip sits in the subchondral bone exactly on the roof of the intercondylar notch, midway between the femoral condyles. In osteoporotic bone, caution should be exercised, since penetration of the thin cortex may occur.

REAMING

The cortices must be at least 3mm thick at any location after reaming, and the intramedullary canal must be reamed to a width of 2mm greater than the lengthener diameter.

The intramedullary canal is reamed by passing the reamer over the guide wire, always starting with a 9mm reamer (Fig. 12). Reaming should then be continued in 0.5mm increments, to a width 2mm greater than the lengthener diameter. Monitor the reaming in both anterior-posterior and lateral planes to ensure that one cortex is not being inadvertently over reamed.

A soft tissue protector should be used proximally. Reaming past the isthmus is necessary as it is important that the ISKD fits freely 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 0.5mm. 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.

**NOTE:** flexible reamers must ALWAYS be used over an olive tipped guide wire; rigid reamers may also be used carefully under image intensifier control.

The guide wire may slip back a little when the reamer is withdrawn. This problem can be helped if the guide wire is lightly tapped prior to reaming, to embed it in the hard cancellous bone above the intercondylar notch. It should also be kept in this position by gentle pressure at the proximal end during withdrawal of the reamer. If the guide wire does become displaced during reaming, it should always be repositioned under X-ray control.

Finally, when reaming is complete, the guide wire should be removed, and the incision irrigated with normal saline to ensure the removal of all fragments of bone, to help prevent heterotopic ossification.

**LENGTHENER INSERTION**

The ISKD end cap is first removed from the lengthener using a 6mm wrench. (It will be replaced after the implant is inserted).

The locking rod is inserted into the back of the handle and the chosen lengthener into the lengthener support, rotating it into the correct position, and the locking rod is then firmly tightened, finally with the 6mm Allen wrench. (Fig. 13)

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”. Screw and drill guides are inserted into one of the holes in the guide bar, and the alignment checked with the 4.8mm drill bit.

The lengthener is now manually inserted, under image intensification with the handle pointing laterally. Ideally, the lengthener should be inserted by hand. The correct depth of insertion has been reached when the step of the lengthener support is at the level of the tip of the greater trochanter.

**Under no circumstances should the insertion of the ISKD require vigorous hammering.**

Twisting the device will activate the distraction mechanism and hard hammering can cause device malfunction. **If the ISKD does not advance easily, it should be removed and additional reaming performed.**
**DISTAL LOCKING**

The locking screws are normally inserted in the coronal plane, and the handle is adjusted to this plane to achieve this. A check is made that the rotation markers are parallel.

Distal locking of the ISKD must be performed using a freehand technique, preferably with a radiolucent drill. Shorter 4.0mm and 4.8mm drill bits are provided for freehand locking.

1) A lateral image is obtained so that the locking holes are seen as true circles. (Fig.14a)

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. (Fig.14b)

5) The drill bit is then advanced through both cortices and the locking screw inserted.

Possible variations of the technique:

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

B) A 2.0mm Kirschner wire can be used for the initial targeting to penetrate the lengthener. When the wire is in the correct position, a cannulated 4.8mm 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 2mm 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 rotate freely and independently of each other, it is important to check for this gap before proximal locking.

The guide locking screws are inserted into the appropriate holes in the femoral guide bar, which is then inserted into the handle. Its position is adjusted until the "P" mark is level with the front surface of the handle. (Fig. 15) Additionally, there is a small ball-bearing in the handle that will help indicate when the guide bar is correctly positioned. The guide bar is then locked in this position. The locking screws are normally inserted in the coronal plane, and the handle is adjusted to achieve this. The correct positions for the locking screws are defined by pushing the screw guides on to the skin.

Two small stab incisions are made, and extended down to the bone with blunt dissection. Two screw guides (17360) are inserted into the holes in the guide bar and pushed in turn down to the bone using the straight trocar. Each screw guide is then locked into position with the guide locking screw.

A drill guide is inserted into the proximal screw guide, and tapped gently to engage its teeth in the bone. A 4.8mm drill guide is inserted into the screw guide. Lock the drill stop on the proximal end of a 4.8mm drill bit. Introduce the drill bit into the drill guide down to the bone before drilling is started. Gentle pressure is applied to the point of the drill bit on the cortex.

The surgeon drills steadily through the lateral cortex. The drill should be stopped when the second cortex is reached. The drill stop is moved down until it is about 10mm above the top of the drill guide, and locked into place. This represents the thickness of the second cortex. (Fig. 16)

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.

Do not drill the second hole before inserting the locking screw.
The locking screw length is determined using one of three methods:
1. using the Locking Screw Depth Gauge: with the end of the screw guide touching the bone, remove the cover from the depth gauge and insert it through the bone. When the hook is engaged on 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 screw guide. (Fig 17)
2. if the drill stop was used as described above when drilling the hole, the drill guide is removed with the drill bit. The correct screw length is the amount of drill bit protruding from the end of the drill guide (ignoring the tapered tip) (Fig 18)
3. using the same drill stop assembly as in (2), the correct length of locking screw can be read directly from the drill bit graduation markings at the top of the drill stop (Fig 18)
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 lateral cortex. Note that there is a circular mark on the T-wrench. This mark will be 7-12mm above the top of the 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.

(Fig. 19) 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, revision screws with a wider, 8.0mm thread are available. Alternatively, the screw should be placed 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. The guide bar is now removed from the handle. While in the operating room, it is advised to distract 2 - 3mm by manipulation, to check that rotation is free from obstruction and that the ISKD is working.

REMOVAL OF THE HANDLE AND CLOSURE

The locking rod securing nut is loosened with the 6mm universal Allen wrench, and removed with the handle, taking care to maintain alignment to avoid damaging the thread on the lengthener. The lengthener end cap provided with the device is screwed into the end of the lengthener, and locked into place with the 6mm Allen wrench.

It is recommended that the insertion area be washed liberally with saline to remove any products of reaming from the wound. This will reduce the likelihood of heterotopic bone formation.

In general, suction drainage should be used in the proximal wound only. The deep fascia should be repaired in all incisions, and all wounds should be closed in layers in the usual manner. Dressings should include a compression dressing and an elastic bandage wrapped around the hip, starting from the foot, in order to avoid wound seroma. The drain is removed after 24-48 hours.
WEIGHT BEARING

Full weight bearing should be avoided. The patient may be mobilized on the first or second postoperative day. Partial body weight bearing (approximately 50% of body weight not to exceed 50lbs/22.7kg) with crutches may be initiated if prescribed and continued throughout the lengthening and consolidation process. Weight bearing may be increased to full body weight as soon as corticalization of the regenerate is evident in 4 of the cortices during the end of 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. A too vigorous program of physiotherapy may be harmful and should only be undertaken under specific order of the physician.

MONITORING 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.

By varying activity levels, the patient should be able to adjust the rate of lengthening. During the distraction phase, the surgeon’s office should contact the patient on a frequent basis to confirm lengthening activity.

Lengthening activity should be initiated by day by day 3 for the femur, as the femur tends to consolidate faster.

The progress of lengthening should be checked regularly against follow-up radiographic evidence of the rate of lengthening and the quality of the regenerate. While 1mm 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. The examination frequency should be considered based on patient progress.
In cases where normal ambulation does not produce adequate lengthening, gentle manipulation of the affected limb can be performed by the patient. 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 lengthener in place. It should not be removed until full consolidation has occurred.

If full consolidation has not occurred and is not imminent by 12 months, the surgeon should begin to think of the possibility of exchanging the device for a standard I/M nail, depending on a variety of factors: the weight of the patient, the amount of weightbearing already carried out and the geometry of the regenerate. This will vary greatly between patients, and the surgeon’s experience is important in making this decision.

**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.
## FEMORAL LENGTHENERS

<table>
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<tr>
<th>ISKD Diameter (mm)</th>
<th>Maximum Distraction (mm)</th>
<th>Start Length (mm)</th>
<th>Max. End Length (mm)</th>
<th>Catalog #</th>
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All lengtheners are provided in sterile packaging.

## ISKD INSTRUMENT TRAY KIT

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<td>1103001</td>
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<td>ISKD Femoral Nail Guide Bar</td>
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<td>External Jig Guide Bar</td>
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FEMORAL LOCKING SCREWS

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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 lengthener 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. (17520).

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: for specific information on sterilization reference ISKD instructions for use.

NOTE: The lengtheners, end caps, and bone locking screws must not be reused.

BIBLIOGRAPHY

6) Raghuram Thonse, MS, DNB, FRCS, John E. Herzenberg, MD, FRCS, Shawn C. Standard, MD, and Dror Paley, MD, FRCS Limb Lengthening with a Fully Implantable, Telescopic, Intramedullary Nail Operative techniques in Orthopaedics, Elsevier, 2005, 355-62
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the IFU Instructions for Use (IFU IU) supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.