



Patient Guide



Intramedullary Skeletal Kinetic Distractor
For Tibial and Femoral Lengthening



Introduction

You have decided to have a limb lengthening operation. The surgery you have chosen uses a device called the ISKD, which stands for Intramedullary Skeletal Kinetic Distractor. The ISKD is unique because it is internal and provides stability and alignment to your bone while it is being lengthened. The ISKD is a two-part metal rod.

The distal (nearest the foot) part is nested inside the proximal (near) part.

During surgery, your surgeon will first separate the bone to be lengthened into two halves by cutting it somewhere near the middle. This is called an osteotomy.

The ISKD is implanted within your bone, and its two parts separate, or distract, over time as you move your limb. When the device distracts, it creates a growing distance between the two halves of bone and encourages new bone to grow in the space. Muscles, skin and other soft tissues will adapt as your limb slowly lengthens.

The ISKD procedure is completely internal or “closed”. There are no external devices, wires or pins needed to lengthen your bone.



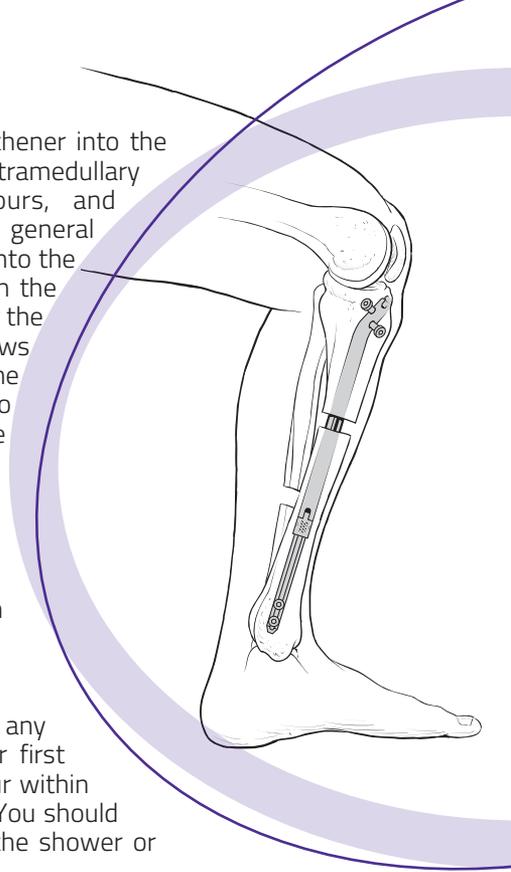
In addition to the information you will receive in this booklet, your surgeon or surgeon assistant will fully instruct you about your role in the lengthening procedure. A successful outcome requires your active cooperation and dedication to certain tasks.



This brochure is for the purpose of information only, and should not be considered a substitute for the care of a healthcare provider.

The Surgical Procedure

The surgical insertion of the ISKD lengthener into the hollow canal of your bone, called the intramedullary canal, takes approximately two hours, and is accomplished while you are under general anesthesia. The lengthener is inserted into the bone through a hole drilled just beneath the knee for tibial lengthening and just below the hip for femoral lengthening. Two screws secure the lengthener in position to the proximal piece of the bone and another two secure it to the distal portion. The bone is cut in the middle prior to the insertion of the lengthener. If the tibia is being lengthened, an opening will be made in both the tibia and the fibula, a smaller adjacent bone. With the ISKD device in place, you will be ready to begin lengthening.



After Surgery

After the surgery, you should not put any weight on your operated leg until your first visit to your surgeon, which should occur within one week after you leave the hospital. You should not allow your incisions to get wet in the shower or bathtub until they are healed.

The lengthening of your bone occurs in two phases: the Distraction Phase, and the Consolidation Phase. During the Distraction Phase, the two segments of your bone are being moved away from each other, and the space between them is filling with new soft bone. The Consolidation Phase is the time during which the newly created bone solidifies enough to support your weight. Weight-bearing is allowed under surgeon discretion.



22 Days



69 Days



EARLY
CONSOLIDATION PHASE

186 Days

Distraction Phase

During the days following surgery, a blood clot forms around the cut ends of the bone at the osteotomy site, and new bone, called callus, begins to form in this clot. The callus joins the two pieces of bone, but is soft and can stretch as the ISKD distracts and separates the two pieces of your bone. All lengthened bone develops from this callus. This early stage of bone development, called the regenerate, is not solid enough to support your weight until later in the healing process. The ISKD lengthener inside the bone supports you partially, but it is important that you do not put all your weight on the leg as that might cause the ISKD to bend or break.

CALLUS FORMATION



When the distraction is complete and the correct leg length is attained, the soft regenerate begins to calcify into hard bone. Your surgeon will use X-ray pictures of your limb to determine when your bone has hardened enough to allow you to place all your weight on your leg again. After that time, you may choose to have the device removed from your leg with another surgical procedure.

Exercises and Lengthening

At the first post-op visit, your surgeon will check your incisions and take X-rays of your leg. You will be trained to put limited weight on the operated leg and shown how to manipulate your limb in order to distract the ISKD. In general, the activities of everyday life combined with controlled ambulation and partial weight bearing should be adequate to produce lengthening. By varying activity levels, you should be able to control the rate of lengthening accurately to that prescribed by your surgeon. Lengthening activities should be initiated by day 5 post-operatively for tibia procedures and by day 3 for femur procedures. In some cases the assistance of a family member or other individual is necessary to accomplish the required exercises with manual manipulation.



3° - 9°
Of rotational
movement will
cause lengthening

Consolidation Phase

Congratulations! You have attained your limb length goal. In this consolidation phase, the regenerate must calcify and harden into bone. This will generally take three to nine months depending upon the amount of distraction that occurred during the lengthening process. The longer the distraction, the longer the consolidation may take. You must remain on crutches until your doctor confirms on X-ray that the two outer edges of the bone shaft have a continuous hard cortical layer. When that bone layer is evident on X-ray, your surgeon will advise you on full weight bearing, without crutches. Your surgeon will want to see you in clinic for follow-up at one month, three months, six months, and twelve months after distraction has been completed.

At these visits, an X-ray of your limb will be taken to assess the progress of bony consolidation. After all four sides of the bone have hardened, you may decide to have an operation to remove the ISKD from your leg.

LENGTHENING GOAL

- 1 mm per day
on average

Frequently Asked Questions

How fast will the lengthening occur?

The duration of your lengthening procedure depends upon how much length you need to achieve, how fast you produce bone, and how accurately you are able to carry out the lengthening activities. The average desired rate is 1 mm per day, although this may vary by individual circumstances. A 2.5 cm (approximately 1 inch) length discrepancy should be corrected in 3 - 4 weeks if you are able to average 1 mm per day of lengthening. The maximum length that can be achieved with a given procedure is 8 cm (or about 3 inches). At that point, the soft tissues become stretched tight and needs some time to adapt before additional length can be gained. If additional length is required, another procedure may be done after approximately one year.

What is required of me during the Distraction Phase?

You, the patient, greatly control the lengthening process. If you exercise your foot or leg sufficiently to comply with your surgeon's recommendations you should obtain 1 mm of lengthening each day and your distraction should occur smoothly. If you are lengthening more than 1 mm per day, you need to your activities. Distraction at too fast a rate can stretch the soft tissues too quickly and cause pain. If you are not achieving 1 mm per day, you should increase your activity. If your distraction rate is too slow, the regenerate might harden to bone before you complete the full lengthening and prevent you from reaching your final goal. In this case, an extra surgery might be required to break the regenerate.



You should avoid any weight bearing for the first week after surgery. After that time, and with your surgeon's permission, you may begin toe-touch, partial weight bearing with no more than 50 lbs/22.7 kg of pressure. Your leg will be vulnerable at the regenerate site until the consolidation phase is underway. Running, jumping, or excessive weight could cause the ISKD to bend.

Starting one week post-operatively, you will need to see your surgeon every two weeks on average, for the entire Distraction Phase. At each visit, an X-ray of your leg will be taken and an examination performed to evaluate your soft tissue (skin, nerves and muscles) for tightness.

What are the possible complications arising from this surgery?

As with any limb lengthening surgery, there is the possibility of premature consolidation, where the soft regenerate becomes hard and the bone stops distracting before full length has been attained. Other possible concerns are contracture, tight soft tissues causing pain, infection, and breakage of the device or the screws. With careful attention to your rehabilitation program and regular, frequent monitoring of your leg by your surgeon at 2-week intervals, most of these problems can be avoided.

How does the device know when to stop lengthening?

The ISKD lengthener size that your surgeon will use for your procedure is determined by an extensive pre-surgical evaluation, including a special set of X-rays to determine how much length you need. Your surgeon's staff will measure the range of motion of your joints and evaluate your body structure to determine that the implant length and the fully distracted length are appropriate for you.

Glossary

Calcify	The formation of calcium phosphate, the dense hard material of bones
Callus	Formation of new bone around a fracture site, a "soft" material formed in the first stages of bone healing
Cortical Bone	The dense, hard outer portion of a bone
Distal	Away from, furthest point of reference (from the head)
Distract	To extend or lengthen
Femur	High bone, largest bone in the body (femoral, femora [pl])
Fibula	The smaller bone between the knee and ankle, on the outer side of the leg
Implant	Device inserted into a tissue for an indefinite period of time and which is not absorbed by the body
Intramedullary	Inside the hollow canal of a bone
Lateral	Outer sides or surfaces, away from the middle or median plane, both right and left
Medial	Middle or median plane, toward the midline, inner surfaces or sides
Osteogenesis	The step by step process of natural bone growth
Osteotomy	A surgical incision into or through a bone
Proximal	Closer to the head, nearest point of reference
Regenerate	New bone tissue growth
Tibia	The large leg bone between the knee and ankle, on the inside of the leg (tibial, tibiae [pl])



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