

PATIENT'S GUIDE

Fitbone™

Intramedullary Lengthening System





Fitbone™

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TAKE CARE OF YOURSELF

Limbs are not always equal in length, not always straight, and sometimes treatment may be considered to correct abnormalities. Treatment options can be non-surgical in non-severe cases, but severe cases may require a surgical procedure to correct the deformity. Your doctor will assess which kind of treatment will be most appropriate for you and may recommend the Fitbone™ Limb Lengthening System.

You are starting a journey with a goal of getting you back to your everyday life. Along the way, you may experience pain and mobility limitations, causing you difficulties with normal daily activities.

Share your concerns, worries and feelings with your care team, including your loved ones. Do not hesitate to call for help when you feel you cannot cope with your difficulties. Remember that your loved ones, the rest of your care team and YOU are all partners in this journey. It is important you take an active role in your treatment; your commitment, determination and collaboration are key in achieving the very best outcome.

We have created this handbook to answer your questions and help you understand what happens before and after surgery. These general guidelines are intended to provide you with a brief overview of the journey ahead.

Always seek the advice of your physician and your care team regarding treatment information and any additional questions or concepts that you want to explore further.

WHAT IS AN INTERNAL FIXATOR

Internal fixation devices such as Fitbone™ are used to correct bone deformities. As the name suggests, they are inserted internally (within the bone) and offer the benefit of a reduced hospital stay, enabling you to return home much sooner than alternative treatment options. During the surgery, your doctor will perform a procedure to insert the Fitbone™ to a pre-planned position. The position will represent the start of your lengthening journey, in which new bone will be formed, correcting your original deformity.

Other internal deformity correction treatments include:

- plates
- nails
- screws
- wires/pins

Nails are inserted into the center of the bone and contain small fixation holes drilled at both ends, in which screws or pins are inserted to help stabilize the bone. For the correction of long bones (such as the femur or tibia), one of the most efficient ways to hold bone segments together is to insert a nail within the segments. The doctor uses an orthopedic drill to create a canal in the center of the bone, known as the intramedullary canal. This canal will be large enough for the nail to be inserted. Screws will be inserted at both ends of the nail to help stabilize the bone segments throughout your lengthening journey.

Recent advances with minimally invasive surgical techniques have allowed patients to regain independence much faster than before. Here, the intra-medullary lengthening nail is completely implanted in the bone as a minimally invasive procedure with only tiny cuts. This has several advantages for the patient: small-to-very small scars and no external fixators, eliminating the risk of infection at the body exit points.

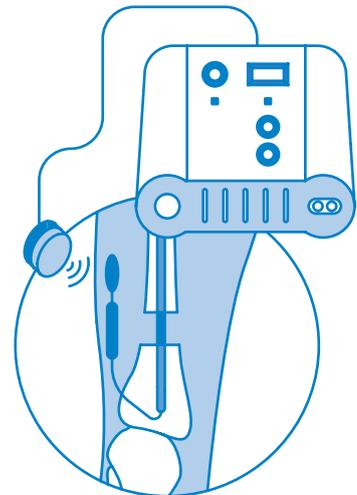
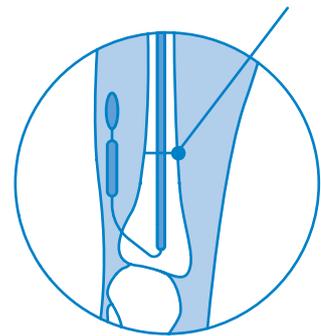
WHAT IS Fitbone™

Fitbone™ is a lengthening nail consisting of a telescopic body driven by an internal motor. The bone is prepared using a series of bone reamers to clear a pathway in the canal, in which the nail is inserted. Before the nail is inserted, the bone will be cut into two parts (osteotomy) and corrective positioning, if required, will be performed.

The surgeon operates through a very small incision and the hospitalization is generally one to three days. The intramedullary nail is fully implantable, meaning there is no evidence of the nail outside of the patient's body, unlike techniques using external fixators. The nail is connected to a discrete receiver positioned just under the skin. Activation of the nail is achieved when the receiver is paired with an external transmitter, which transfers a safe electrical impulse from a control set. This engages the motor within the nail, extending the nail body and lengthening the bone. The patient (or family member) may need to repeat this action several times a day (for more specific info on the post-surgery care, please refer to page 23).

Limb lengthening is a gradual technique that can help correct the results of irregular bone growth, or help repair damage from an accident, bone loss or a non-union (a fracture that has not healed properly).

OSTEOTOMY

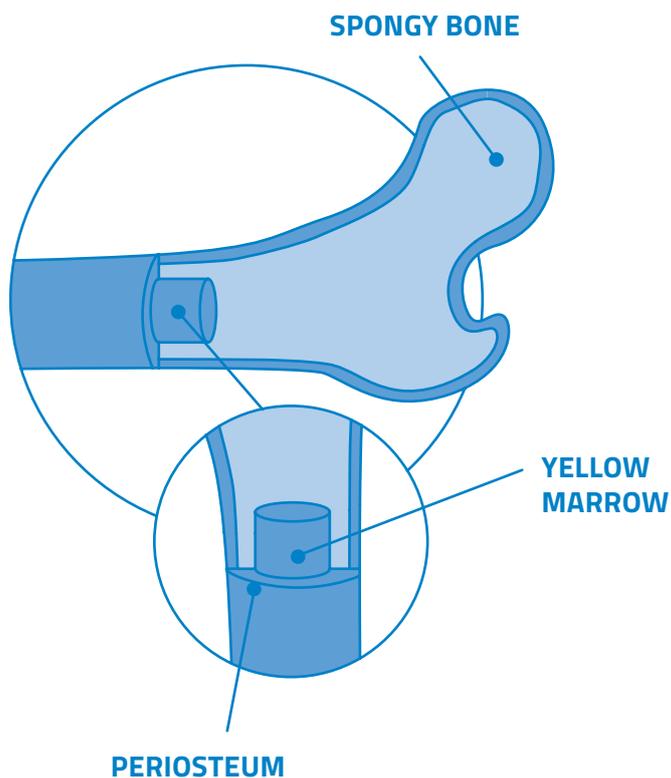


THE BONE HEALING PROCESS

A broken bone is called a fracture. In order for a fracture to heal, the bones must be held in the correct position and protected. Soon after a fracture occurs, the body acts to protect the injured area and forms a protective blood clot and callus around the fracture.

New “threads” of bone cells start to grow on both sides of the fracture line. These threads grow toward each other as the fracture closes and the callus is absorbed. Your proposed treatment takes advantage of the natural physiological process of fracture healing.

The callus can be manipulated to achieve a variety of objectives. The lengthening nail can be used to lengthen the callus mass (and hence the bone) by a process of slow, symmetrical distraction.



UNDERSTANDING LIMB CORRECTION

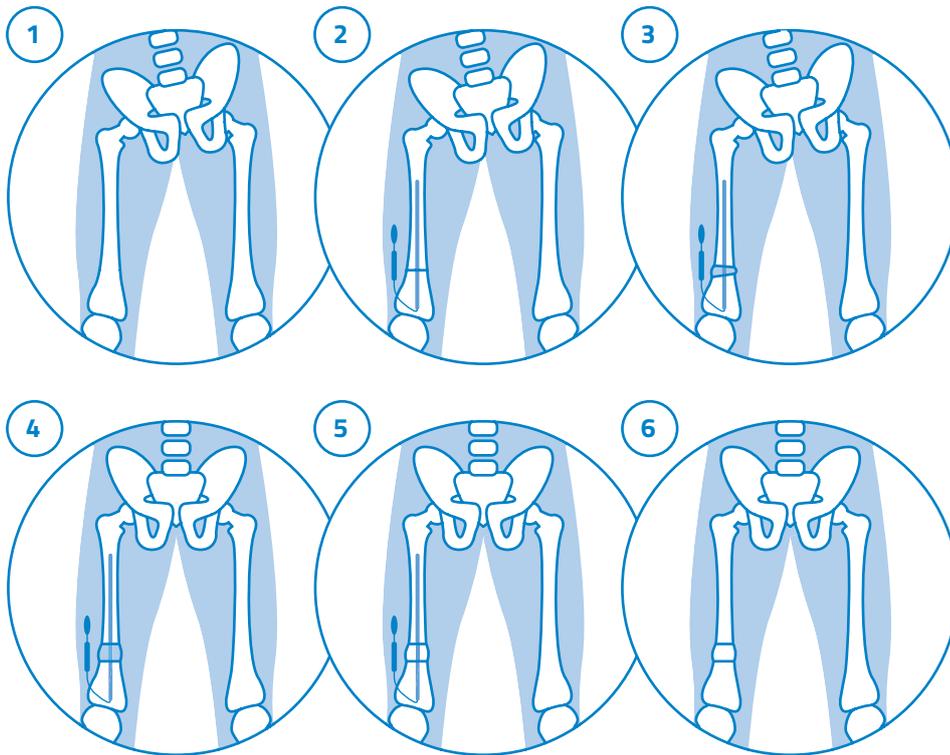
Bone deformities are surgically treated by bone correction or bone lengthening procedures. The surgeon creates a cut across the affected bone, prepares it to receive the orthopedic device, and implants the device to assist with your bone correction. This procedure is called osteotomy and may be performed with either internal or external fixation devices to stabilize the target bone.

Limb deformity correction devices that remain outside of the body are called “external fixator devices”, whereas those that are inserted into the bone or directly over the bone are called “internal fixator devices”.

The process of slowly separating and straightening the bone segments is called **distraction**, which means “to pull apart”. The distraction process helps create a space that allows for new bone to grow in between, thus straightening the affected bone.

Distraction is achieved through a planned schedule of nail activation, which is initiated daily by the patient or care giver. This slowly extends the nail, lengthening the bone and correcting the deformity. The patient will be asked to see the doctor at scheduled time periods and have additional x-rays to make sure the bone correction proceeds as planned. During this phase, the patient will also be asked to attend physical therapy sessions as instructed by the doctor.

Following the distraction phase is the consolidation phase, where the new bone starts to harden. The bone is healed when the new bone has completely hardened and calcified. The consolidation phase takes approximately twice as long as the distraction phase. Thus, if distraction is completed in 1 month, then consolidation will take 2 months. The patient may be asked to gradually apply more weight to the affected area, which encourages new bone growth.



- 1) Leg length discrepancy
- 2) Surgery
- 3) Latency phase: initial callus formation
- 4) Correction
- 5) Consolidation
- 6) Implant removal

ROLES OF THE CARE TEAM

1) Patient

You are the most important member of the care team, and will need to be active in the process both before and after surgery to help your limb heal. Tasks will include activating the motor inside the nail several times a day using a special device provided by your surgeon, performing physical therapy exercises, and possibly others as instructed by your surgeon and other members of the care team. You should also ask questions to your surgeon and other medical professionals to ensure you fully understand each step and to help your care team meet your needs. Share your concerns so your surgeon, nurses and physical therapist can make your recovery as smooth as possible.

2) Surgeon

Your surgeon will be with you beyond the initial evaluation and surgery, so it is important to build a two-way relationship that will let you communicate throughout the process. Your surgeon will help you create a recovery plan and will see you at certain times, to ensure your treatment is progressing as intended.

3) Family and Friends

You will need help at home. Involve your family or close friends from the start so they can understand the procedure as well as you do. Your family and close friends may be able to help you plan for surgery and recover from it. For example, they may help you with physical therapy exercises.

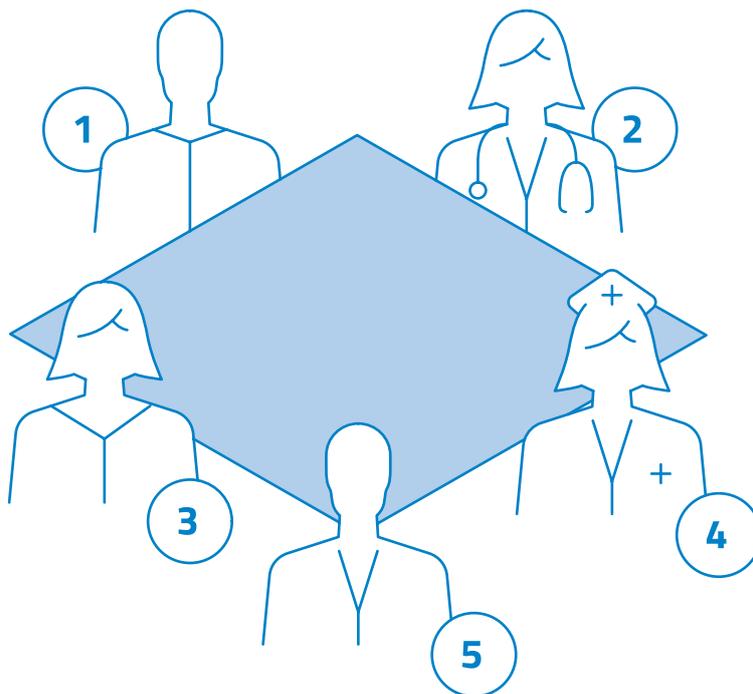
4) Hospital team

Nurses and other medical professionals in the hospital will assess your health status before surgery. They will coordinate your hospital stay on the day of surgery and after surgery, and be there to guide you through each phase of your treatment until you are able to go home.

The nursing staff will help control your pain and teach you about caring for yourself after surgery. Don't be afraid to ask your nurses questions about the surgery process or to express your concerns before or after surgery.

5) Physical Therapist

Your physical therapist will assess your movement ability before surgery and will work with you throughout the process to help you stay as active and independent as possible. After surgery, the physical therapist will teach you exercises to do both in the hospital and at home, and give you a plan for getting you back on your feet. You may see the physical therapist on a regular basis to check your progress and to make any changes to the plan.



PREPARING FOR SURGERY

In order to make the limb correction process work, you must prepare for your journey. Here are some considerations to work through with your surgeon and family.

Consulting with your surgeon

Your surgeon should explain why the lengthening nail has been recommended, the full details of the surgery, and the benefits and risks of surgery. It is important to remember that all surgeries, including surgery to apply a lengthening nail, have some risks.

No amount of questions is too many. Your doctor and his/her care team are there to answer any queries that you may have. Therefore, feel free to initiate a frank discussion with your doctor. Some questions you might want to ask are as follows:

- *What are the benefits of this procedure?*
- *How long will the benefit last?*
- *When will healing be complete?*
- *What are the risks and complications?*
- *What can I do to decrease my risk for complications?*
- *What is the success rate for this procedure?*
- *What are the chances that more surgeries will be required in the future?*
- *What is the percentage of improvement following the procedure?*
- *Can this surgery be delayed? What happens if I don't have it immediately?*
- *What tests will be performed prior to the surgery?*
- *Will the surgery be done under general or local anesthesia?
Are there possible side effects or risks of the anesthesia?*
- *How much pain will I have following the procedure?
What pain relief or pain control measures will I be given?*
- *How long will the recovery take? Will I need assistance at home afterwards? Do I need to prepare my home in some way for post-surgery period?*
- *When can I return to school/work and get back to normal life?*



Communicating with your insurer

Because medical insurance may be key to receiving the treatment you need, it is important to communicate with your insurer to confirm whether or not your surgery and potential after-care situations will be covered.

Check your policy to see what services are and are not covered. You can request this information from your insurance company. You and your surgeon can also submit paperwork to the insurance company for “pre-certification” to ensure there are no surprise bills after surgery. If you are pre-approved, your insurance company will let you and your doctor know. At the time of surgery, you pay the co-pay or deductible and your insurance should pay the rest.

However, sometimes your insurance company may deny coverage, even after pre-certification. This can be for reasons other than what is covered by the insurance policy, such as exceeding your benefit allowance. If pre-certification is denied for other reasons, such as restrictions on treatment (for example, the procedure is covered, but for a different diagnosis) or a determination that the treatment isn’t “medically necessary,” you may still be able to get insurance coverage. You can start by appealing the decision with the insurance company, which must provide you with all information about the process. By getting this information and following the process, you may be able to have a denial overturned.

Planning ahead

The amount of time the lengthening nail will be in place depends on the severity of the deformity, how much correction is needed, and your general health and medical history. Factors such as age, smoking status, nutrition status and mobility levels can influence healing. Your surgeon will provide expected time frames according to your specific situation.

The following is a checklist of items to bring with you to the hospital:

- A list of all medications that you are be taking.
- Your insurance card.
- Your primary contact details while you are in surgery.
- Do not bring any valuables.

You may be allowed a small suitcase/bag where you may keep comfortable clothing, toiletries etc. Bring anti slip, yet comfortable, footwear to avoid accidental falls.

Possible risks related to the surgical intervention are:

- Injury to blood vessels, nerves, muscles or tendons. The consequences can be circulatory disturbances, functional disturbances, sensory disturbances, nerve pain, paralysis of the leg or a loss of the limb. Reconstructive interventions may be necessary.
- Thromboses, embolism with respiratory distress, lung damage and even death.
- Bone, soft tissue or joint infections.
- Swelling and possibly bleeding of soft tissue, compartment syndrome.
- Severe local circulatory disturbances which can lead to loss of limbs.
- Numbness around the scar.
- Hyperreactions of the skin.
- Positioning injury to the healthy limbs, buttocks or head.
- General infections up to blood poisoning.
- Risks related to blood transfusion (e.g. HIV, hepatitis).
- Damage to growth plates in children and adolescents, growth defects with bone deformities.

Possible risks connected to a distraction treatment following the surgery for leg lengthening include:

- Functional limitations of the limbs.
- Delayed or missing bone fracture healing. Spongiosaplasty may be necessary.
- Joint injury, subluxations, luxations, joint stiffening, femoral head necrosis.
- Allergic reactions or other intolerance reactions to the implant material.
- Remaining or re-emerging shortening, remaining axial and torsional misalignment and, if necessary, further surgical correction.
- Infection around the implant components with the need to surgically remove them.
- Loosening of the intramedullary lengthening nail.
- Osseous eruption of the the intramedullary lengthening nail.
- Refraction of the bone after explantation of the implant.
- Too frequent or excessive distraction can lead to overstretching of the nerve fibres, which, in some cases, can result in temporary nerve damage or permanent paralysis.
- Bone fracture at the end of the locking screw.
- Contracture of the knee, ankle and hip flexor muscle.
- Delayed consolidation.
- Valgus deformity.
- Possibility of an over- or under-correction.

System-related risks:

- Dysfunction of the intramedullary lengthening nail or receiver with necessity of a re-operation to replace the components.

At the end of treatment, the deformity or the original problem may not be completely corrected. It is best to discuss this with your surgeon who can provide you the best information and guidance on the expected success rate for your procedure.

CARE AFTER SURGERY

Living with your Fitbone™

During your treatment, there may be some modifications to the things that you can do, but you should find that the lengthening nail does not interfere too much with your normal life.

Before you are discharged from the hospital you will receive information about weight bearing and mobility. You may require a wheelchair or crutches, depending on the treatment you have had. A load of up to 20 kg on the affected leg is typically permitted. Stacked shoes are used to compensate for differences in leg length. Your physiotherapist will teach you how to use these and advise you how to reduce any mobility difficulties you may experience at home during this time. As healing progresses, your leg will become stronger and your physician may advise an increase in the load you can place on your leg.

Physical therapy is initially limited to the prevention of pulmonary and thromboembolic complications. Exercising of the knee joint typically starts from the fourth post-operative day. Always follow the physical therapist's instructions.

The distraction phase will typically start 5 days after your surgery. Your surgeon will give you a special device and advise how to lengthen the nail through the activation of the motor.

You may need to repeat this action several times a day to reach the planned bone lengthening as prescribed by your surgeon. This allows lengthening of your bone at a comfortable rate, letting your new bone grow in the surgically created space. Lengthening too fast may mean that new bone cannot grow fast enough and this will cause problems with bone healing. Lengthening too slowly may result in premature bone consolidation before complete lengthening is achieved.

By taking regular x-rays of your bones, your doctor will ensure that the lengthening isn't happening either too fast or too slowly. You may be asked to change the rate of correction as a result. Your surgeon will explain the schedule and how many visits will be needed.

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. Once your surgeon is satisfied that sufficient bone healing has taken place, the device will be removed from your leg with another surgical procedure.

At discharge

You may ask your healthcare team to provide all instructions in writing. Your post-surgery list of the medications should also be explained in detail. Feel free to ask questions if you do not understand your medication regimen or any instruction. Other practical pointers include:

- Have a family member present as the nurse gives you instructions to help recall what was said.
- Questions you may ask can be around:
 - > When to see the doctor again
 - > Dates and times if nurses or therapists will come to assess you at home
 - > When to change your bandages
 - > When bathing is permitted
 - > When it is okay to be alone in the house
 - > When you can drive
 - > Instructions about elevation of an operated extremity and weight bearing on the affected limb.

- Make sure to understand all signs of complications, such as infections or blood clots. Know how to quickly contact your doctor or healthcare team should you notice signs of complications and keep the contact details handy at all times.
- Be mindful that sleeping pills and pain medications can cause unexpected balance problems.

What you will need for your trip home: you may wish to travel home with a cushion for additional comfort. In addition you should include the loose-fitting clothing, proper, non-skid shoes. These items can be brought in by a family member on the day of discharge.

Pain Relief

You may experience some discomfort after leaving the hospital. This is normal, and likely due to being more active at home than in the hospital. Pain will decrease over a few weeks. In the meantime, you can take the painkillers that have been prescribed, according to need and instructions. If pain increases acutely or does not go away as expected, contact your surgeon. As the pain decreases, you can eventually stop taking the painkillers.

Exercises and physical therapy

A physical therapist will teach you exercises post-surgery at a time decided by your doctor. Your care giver may also be taught these exercises to assist you in performing them.

Physical therapy exercises should be performed according to the instructions of your physical therapist. Performing them at the rate specified will help strengthen the muscles, joints and bones by preventing joint stiffness. It is crucial to do these exercises. Please be mindful, however, to follow the rate of exercise only as per your therapist's instruction.

Following physical therapy instructions is extremely important so you can enjoy the maximum benefits of surgery. Bear in mind that excessive exercise may also be harmful. Always follow the physical therapist's instructions.

The target areas for physical therapy after surgery include:

Strength: strengthening the muscles that support your affected limb facilitates its healing.

Keeping these muscles strong can help prevent further injury.

Flexibility: stretching the muscles is important for restoring range of motion and preventing injury.

Activity

- Good quality sleep is a great recovery tool. Try and rest whenever you feel tired.
- Increase your activity only as recommended by your doctor.
- Avoid putting weight on your repaired bone until your doctor says it is okay.
- Do not shower for 1 or 2 days after surgery. When you shower, keep your dressing and incisions dry.
- Do not take a bath, swim, use a hot tub, or soak your affected limb until your incision is healed. This usually takes 1 to 2 weeks, but will be specified more clearly by your doctor.

Incision care

You may have tape placed on the incision site. Keep the tape in place until the doctor allows you to remove it or it naturally falls off. When your doctor allows you to remove the bandage, you may clean the incision site with soap and water unless your doctor gives you different instructions.

Ice and elevation

You might be asked to prop up the injured leg on a pillow as you ice it or anytime you sit or lie down during the first 1 to 2 weeks after your surgery.

Follow-up care is a key part of your treatment and safety

Be sure to make and go to all appointments and call your doctor or nurse call line if you are having problems.

Other medications

Talk to your physician to understand if you can continue to take your regularly prescribed and over-the-counter medications after the surgery. Be sure to disclose all prescriptions and over-the-counter medications that you take.

Back to work

Your return to work will depend on several factors: the type of work you do, the severity of your condition, how you get to work and the treatment plan after surgery. You should discuss returning to work with both your surgeon and your employer.

Back to school

Adolescents should move as much as possible and should return to school as soon as safely possible, depending on the severity of the child's condition and the treatment plan after surgery. Discuss a timeline with your child's surgeon. In addition, it will be helpful to discuss the child's after-surgery needs with the school so that any necessary arrangement can be made.

Vacation

This depends on the type of treatment you are having and whether you will be flying. Speak to your surgeon's office for advice. Get a letter from your surgeon to pass through security at the airport with the orthopedic device in place or with medicines related to the surgery.

FAQ

1. What are internal orthopedic devices?

Internal fixation is when the device corrects the bone by being completely inserted inside the bone. The advantages of internal fixation include shorter hospital stays and enabling you to return to normality sooner when compared with other methods. During the surgery, the doctor implants the internal fixator device to keep the bone in the corrected position as it heals.

2. How long will the device be in place?

Internal fixators are removed after new bone formation is complete. This is typically between a time period of 12-18 months.

3. What are the signs of infection to look out for?

A nasty odor from the affected site is an immediate indicator of a problem as well as a fever developing in the days immediately after the surgery. Any kind of redness or inflammation around the surgical site is also not to be ignored. Call your doctor immediately if any signs of infection develop post-surgery.

4. What is a limb lengthening nail?

An intramedullary lengthening nail is a fully implantable limb lengthening system for correcting leg length discrepancies and limb deformities. It requires a minimally invasive surgery which provides great results with minimal scarring and a shorter hospital stay compared to other surgical limb correction procedures.

5. How does a lengthening nail function?

The lengthening nail is one of the components of a complete limb lengthening system. A handy control set is provided to the patient, who presses a button to activate the lengthening process.

6. What are the advantages of a limb lengthening nail system?

The system can produce the same results as an external fixator, but with a number of advantages: minimally invasive, minimal scarring, and the absence of a large external metal frame, which requires manual lengthening adjustment. To the patient this provides enhanced comfort and a quicker return to normality post surgery.

7. How fast will the lengthening occur with a lengthening nail such as the Fitbone™?

One session of distraction includes 9 impulses which are delivered from the device by the patient pressing the "Patient" button. Each session lasts for about 90 seconds. On average, 27 impulses equal to 1mm of lengthening. The number of impulses required, and their frequency will be set by your surgeon.

8. What is required of me during the distraction phase with a lengthening nail such as the Fitbone™?

You would be required to adjust the lengthening of the nail at the frequency prescribed by your doctor. Distraction begins around the fifth postoperative day, at the instruction of the surgeon. The rate of distraction depends on the expected or radiologically detectable bone regeneration and the soft tissue conditions. Lengthening is initiated by simply pressing the patient button on the control set.

9. How does the lengthening nail know when to stop lengthening?

The device has an inbuilt system which automatically stops after every 9 impulses. If your surgeon asks you to perform more than 9 impulses then you may reset the control set after the first round and initiate the process again. 27 impulses equal to 1mm of bone lengthening.

10. Is there a risk for me to over-correct the bone deformity?

It is crucial to follow the frequency of adjustment as specified by your doctor. Do not perform more adjustments in hope of speeding up the lengthening process. This will do more harm than good. As for the frequency of impulses delivered in one adjustment session, the device is designed to not allow over-correction of the deformity.

11. What is the maximum bone lengthening achievable?

Typically, 80mm of maximum limb lengthening is possible.

12. Can bone lengthening be performed on both legs at the same time?

Bone lengthening may be performed on both legs, however not simultaneously. After one lengthening adjustment session has been completed on one leg, the other may be performed.

13. Do I have scar tissue left after the procedure?

The bone lengthening process using a lengthening nail system is a minimally invasive process with very little scar formation.

PATIENT DATA



My pre-admission clinic visit

Date _____

Time _____



My surgery date

Date _____

Time I need to be at hospital _____

What to bring to the hospital? _____



Contact

Contact _____

Info _____

The Limb Lengthening Process

PRE-SURGERY

Care-team members

1) PATIENT

You are the most important member of the care team, and will need to be active in the process.

2) SURGEON

Your surgeon will be with you beyond the initial evaluation and surgery.

3) FAMILY AND FRIENDS

You will need help at home along the way. Involve your family or close friends from the start.

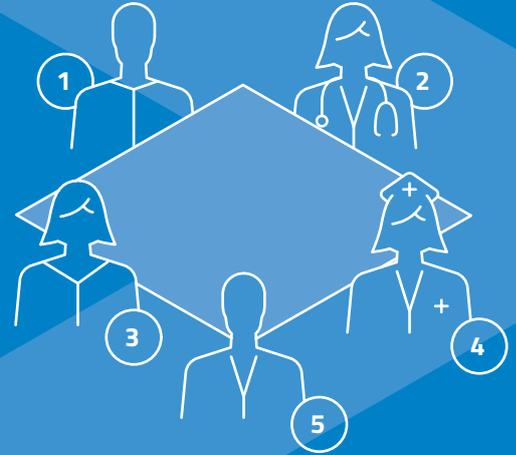
4) HOSPITAL TEAM

Nurses and other medical professionals in the hospital will assess your health status before surgery.

They will coordinate your hospital stay on the day of surgery and after surgery.

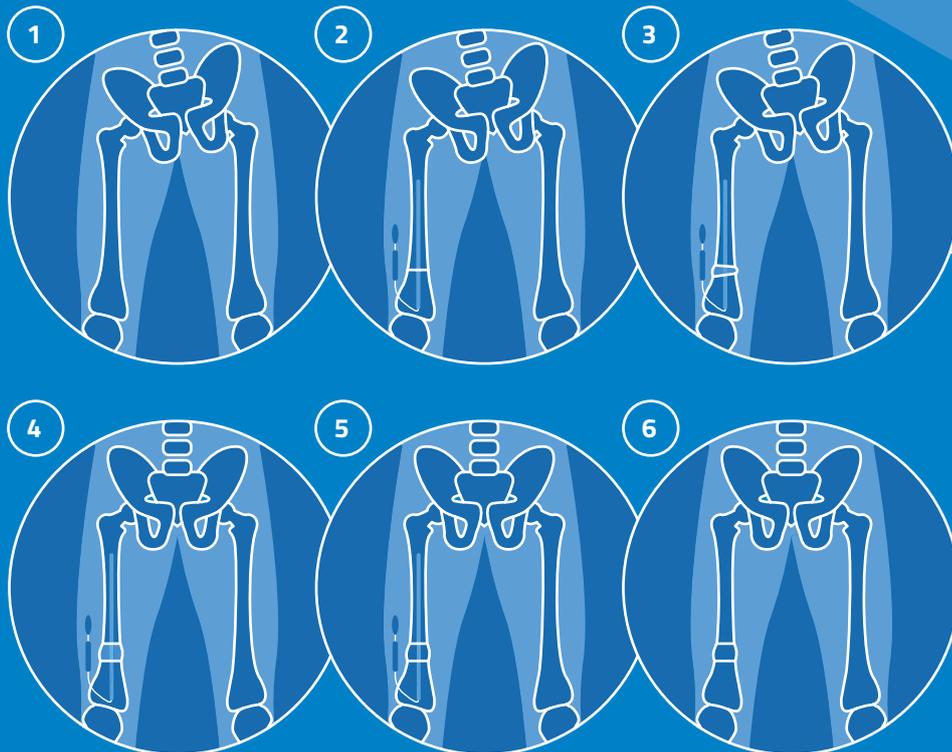
5) PHYSICAL THERAPIST

Your physical therapist will assess your movement ability before and after surgery.



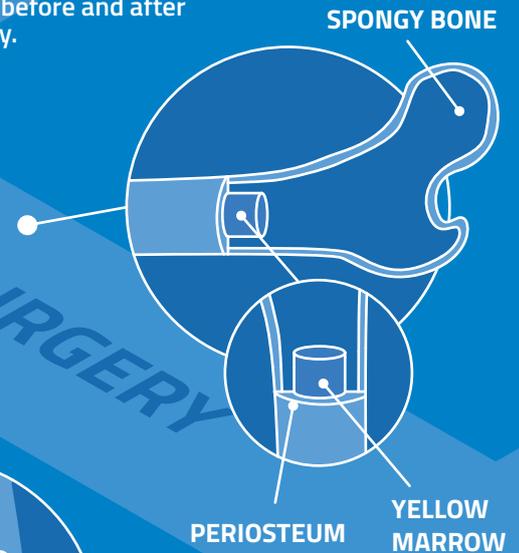
PRE-SURGERY

Understanding limb correction



- 1) Leg length discrepancy
- 2) Surgery
- 3) Latency phase: initial callus formation
- 4) Correction
- 5) Consolidation
- 6) Implant removal

PRE-SURGERY





SURGERY

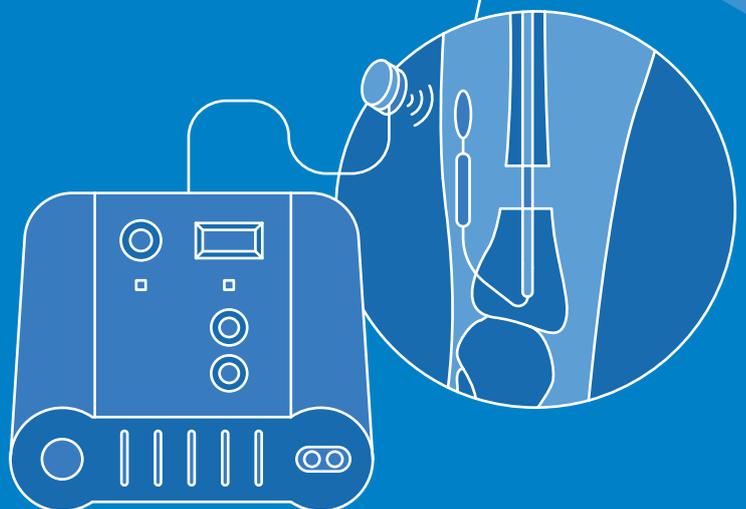
POST-OPERATIVE PHASE

POST-OPERATIVE PHASE

Limb Lengthening

Soon after your surgery, you will be shown how to activate the motor inside the nail. This will allow the lengthening of the nail and of your bone.

You may need to repeat this action several times a day to reach the planned bone lengthening as prescribed by your surgeon.



Fitbone™

Intramedullary Lengthening System



END OF TREATMENT

Implant removal

When the distraction is complete and the correct leg length is attained, the soft regenerate begins to calcify into hard bone.

The nail is removed after 1 - 1.5 years.

END OF TREATMENT

POST-OPERATIVE PHASE

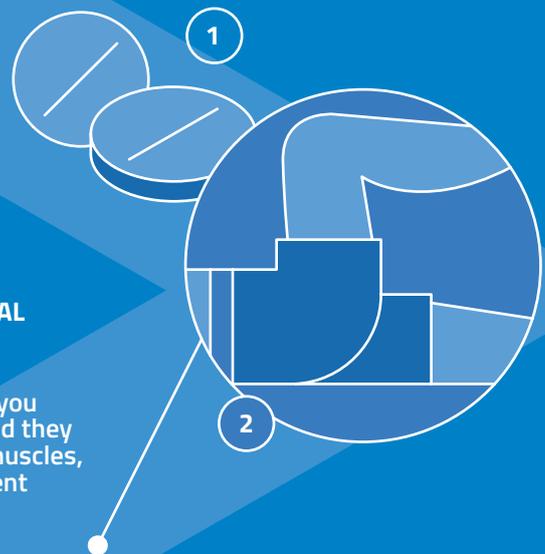
Living with your Fitbone™

1) PAIN RELIEF

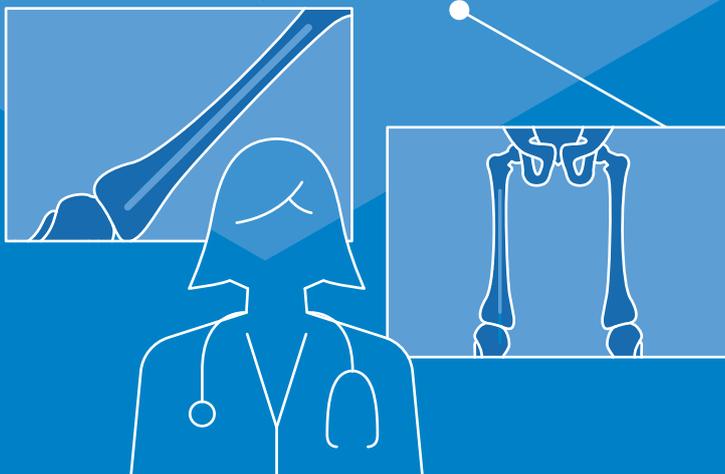
Pain will decrease over a few weeks. In the meantime, you can take the painkillers that have been prescribed

2) EXERCISES AND PHYSICAL THERAPY

Exercises will be taught to you by your physiotherapist, and they will help strengthen your muscles, joints and bones, and prevent stiffness and contractures



PHASE



POST-OPERATIVE PHASE

Follow-ups

FOLLOW-UP CARE IS A KEY PART OF YOUR TREATMENT AND SAFETY

By taking regular x-rays of your bones, your doctor will ensure that the lengthening isn't happening either too fast or too slowly and may ask you to change the rate of corrections as a result.

Your surgeon will explain the schedule and how many visits will be needed.



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Manufacturer info is available
on the product labels and relevant IFUs.