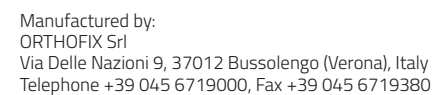


TrueLok Hexapod System®

A man with a beard and a black cap is riding a red mountain bike over a white ramp. He is wearing a black t-shirt and blue jeans. The background is a clear blue sky. The image is part of a magazine spread, with the left page showing a close-up of a person's face and the right page showing this full-body action shot.



CE 0123 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.

www.limbhealing.com
www.orthofix.com

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Visualization of a team journey

Patient

Surgeon

Family & Friends

Psychologist

Nurse

Physiotherapist

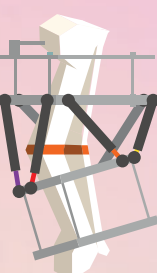
Surgery
(operative room)



Bone deformity

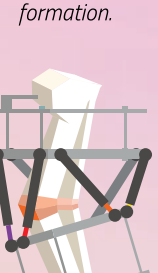


Surgery

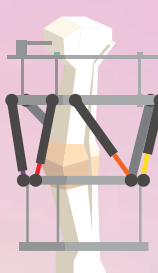


Latency

Initial callus formation.



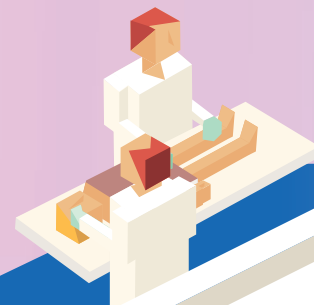
Correction



Consolidation

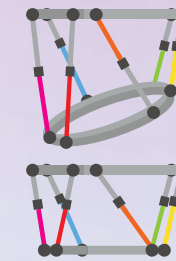


Implant Removal



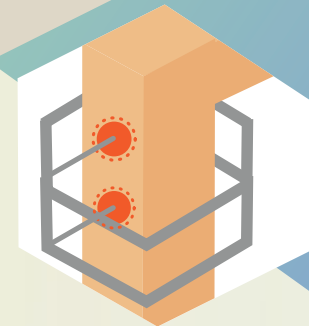
Excercises and Physiotherapy

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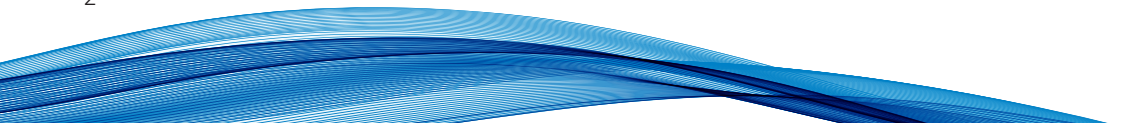
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TAKE CARE OF YOURSELF

When a limb needs to be lengthened, or a problem needs to be corrected, there are several non-surgical and surgical treatments available, depending on the severity of the issue and the history of treatments that have already been done. Your physician or orthopaedic surgeon has assessed your treatment needs and has decided that the external fixation device named TL-HEX is the best treatment for you or your loved one.

You are starting a journey, which the goal is to allow you (or your loved one) to get back to your everyday life. Along the way, you may experience pain, difficulties with mobility and limitations on play or work and normal activities.

Share your concerns, worries, feelings with your care team and with 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 care team and YOU are partners in this journey. It is important of taking an active role in your treatment: its success also depends on your attitude and collaboration.

To help answer your questions and help you understand what happens before and after surgery, we have created this handbook. These can only be general guidelines and they do not expect to be exhaustive.

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



WHAT IS EXTERNAL FIXATION?

An external fixation device is worn outside the body. This device, which is called a fixator, is connected to the bone with bone screws (commonly called pins). The pins pass through the skin, and sometimes muscles, to connect the external fixator to the bone, in order to hold the bone in place and to anchor the fixator securely. Sometimes wires are used with or instead of pins to hold the bone pieces in place. External fixation is used for temporary stabilization, fracture treatment and treatment of deformities that have arisen after healing from trauma injuries.

Limb lengthening and **limb correction** are gradual techniques that can help to correct the results of irregular bone growth that occurred in childhood, or help to repair the damage from an accident, bone loss or a non-union (a fracture that has not healed properly).

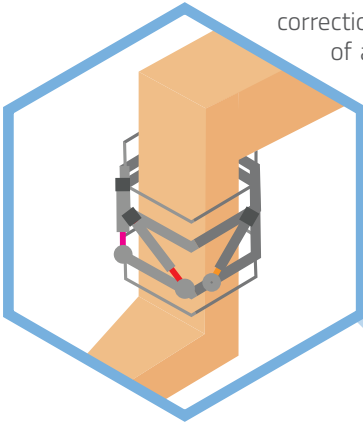
The bone is corrected in these procedures by carefully cutting the bone (osteotomy) and then slowly lengthening or correcting the limb. The surgeon uses the external fixator to place the bone in correct position and alignment until bone healing occurs and deformity correction is achieved.

The bone is corrected in these procedures by carefully cutting the bone and then slowly lengthening or correcting the limb



WHAT IS TL-HEX?

TL-HEX is a 3D external fixation system that combines hardware and software to correct bone deformities. In essence, the system consists of circular and semi-circular external supports secured to the bones by wires and half-pins, and interconnected by six struts. Successful application and correction of the deformity or injury also relies on the use of associated software, which incorporates imaging to determine the precise measurements and positioning of TL-HEX. This combination of hardware and software allows for simultaneous adjustment of the external supports at multiple angles.

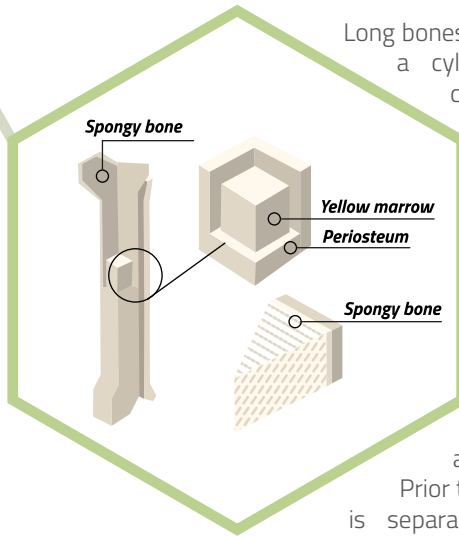




THE BONE HEALING PROCESS

All bones have an exterior layer called cortex that is smooth, compact, continuous, and of varying thickness. The internal part of the bone is really similar to a sponge and is defined cancellous or trabecular. In mature bone, all the internal structures are organized in order to provide maximal rigidity with minimal material and their pattern can be described as a series of lines almost parallel.

Bones such as vertebrae, usually have thin cortices and provide necessary structural rigidity through trabeculae, whereas bones such as the femur, defined as long bones, are subject to prominent loads and usually have thick cortices, a tubular configuration, and a continuous cavity running through their centres (medullary cavity).



Long bones, have an unique and specific shape: a cylindrical conformation across the central region with a thick cortex and at one or commonly both ends, an enlargement that is made by trabecular bone (typically cancellous). This region (metaphysis) transfer loads from weight-bearing joint surfaces to the diaphysis. Finally, the third part of the long bone structure (so called epiphysis) comprises the cartilages and usually displays a rounded shape where two adjacent bones come in contact.

Prior to full skeletal maturity the epiphysis is separated from the metaphysis by a cartilaginous plate called the growth plate or physis.

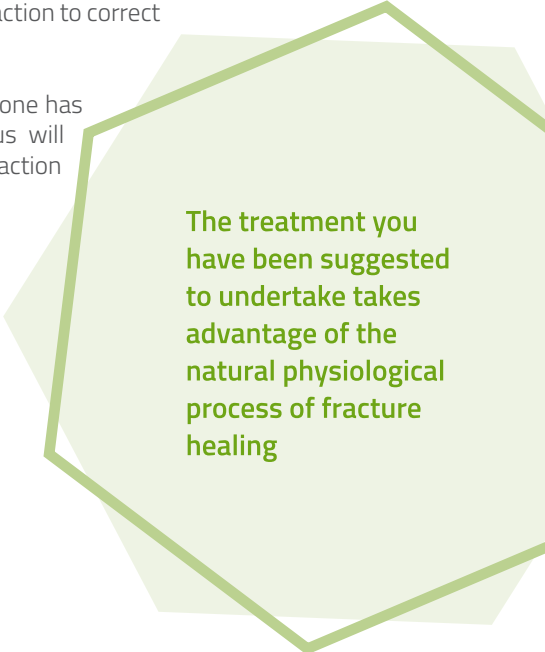
Periosteum, fibrous membrane covering the surfaces of bones, consisting of two layers: the outer more fibrous and the inner cellular. The relevance of the outer surface is related to the presence of nerves, that cause pain when the area is damaged.

The inner layer of the periosteum contains cells apt to produce new bone (osteoblasts) and is most prominent in fetal life and early childhood, when bone formation is at its peak. In adulthood these cells are less important, but they retain

an important function: the capability to remodel and rebuild the bone throughout life. In the event of bone injury, they proliferate greatly to produce new bone in the repair process. Following an injury such as a fracture or when the bone is fractured by intention (osteotomy), the periosteal vessels bleed around the traumatized area, and a clot forms around the fragments of bone (bone callus). Within two days the osteoblasts multiply to create a thick layer that expands and solidify. After this initial activity, the cells start to differentiate in order to build new bone.

The treatment you have been suggested to undertake takes advantage of the natural physiological process of fracture healing. The callus can be manipulated to achieve a variety of objectives. The external fixator can be used to lengthen the callus mass (and hence the bone) by a process of slow, symmetrical distraction, or by slow asymmetrical distraction to correct a deformity.

After a suitable waiting period after the bone has been cut, to ensure that sufficient callus will have formed within the fracture gap, distraction is commenced.



The treatment you have been suggested to undertake takes advantage of the natural physiological process of fracture healing

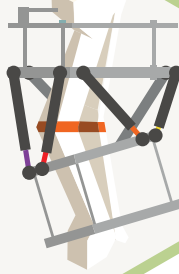


UNDERSTANDING LIMB CORRECTION

**Bone
deformity**

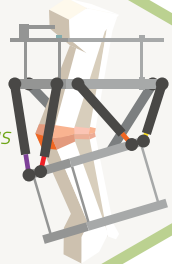


Surgery



Latency

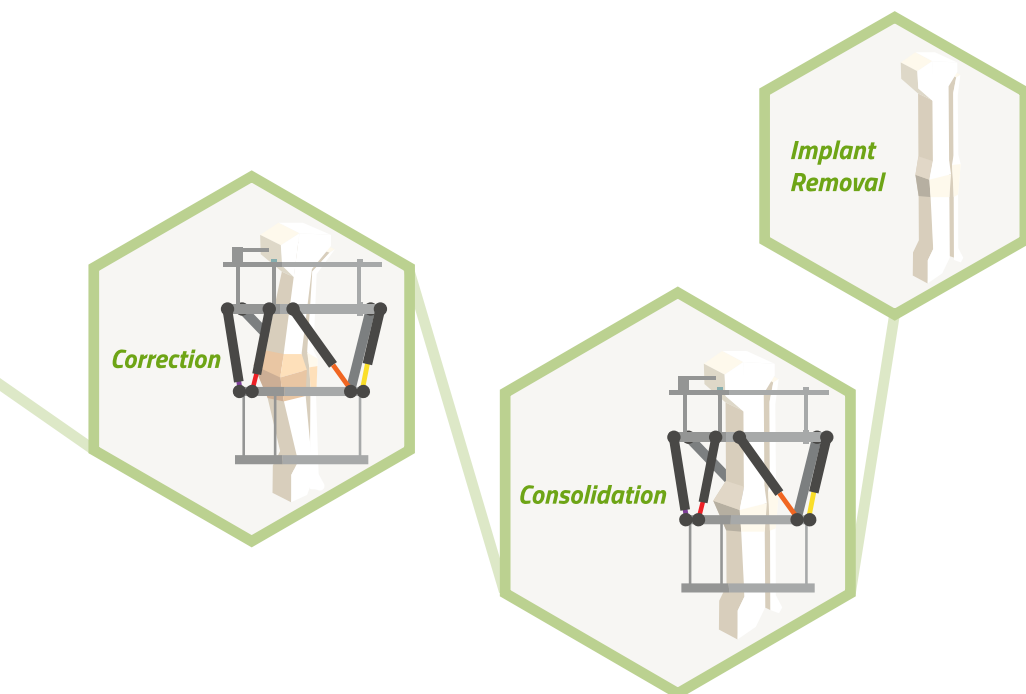
*Initial callus
formation.*



**Soon after your
surgery, you will be
shown how to adjust
the length of your
fixator frame**

The bone deformity must be **corrected**, and/or the bone lengthened. The new bone that grows is then allowed to strengthen and harden in the new shape/length. This second step is called "**consolidation**." Your surgeon will be able to give you an estimate of how long these two stages will take, depending on your specific health situation, but external fixation is usually in place for 4 to 12 months.

While the deformity is being corrected, the external fixator will need gradual adjustments, to help new bone tissue grow into place over time. Soon after your surgery, you will be shown how to adjust the length of your fixator frame.



When your surgeon is happy with the length, shape and alignment of the bones, adjustments will no longer be needed. However, you will still wear the external fixator, which will support your limb while the new bone tissue hardens and the limb becomes stronger. A good rule of thumb to remember is that consolidation takes twice as long as lengthening/reshaping.

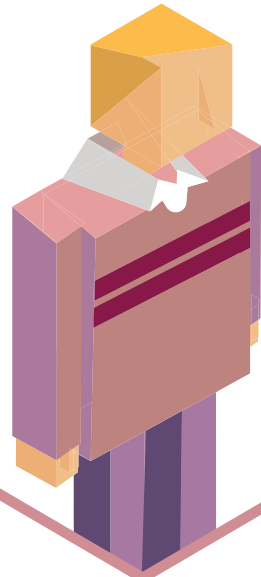
Before having surgery, it's important to do more than simply read information. Use patient education materials and websites such as www.limbhealing.com to help you and your family come up with questions that you will ask your surgeon, nurses, physical therapist and other medical professionals. You may also want to speak to patients who have had external fixation.



ROLES OF THE CARE TEAM

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 adjusting the external fixator, caring for the pin sites, performing physical therapy exercises, and others as instructed by your surgeon and other members of the care team. You should also ask questions of your surgeon and other medical professionals, to ensure you fully understand each step of the way — and to help your care team meet your needs. Share your concerns, so that your surgeon, nurses and physical therapist can make your recovery as smooth as possible.





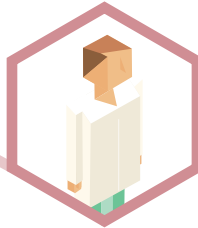
Surgeon

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 along the way, to ensure your treatment is progressing as intended.



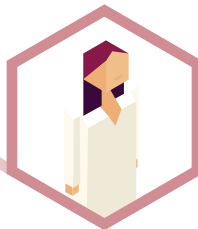
Family and Friends

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



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 — nurses can help you with and advise you on a range of issues.



Physical Therapist

Your physical therapist will assess your movement ability before surgery and 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 see how you are progressing and to make any changes to the plan.



PREPARING FOR SURGERY

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

Consulting with your surgeon

Your surgeon has explained the reason external fixation 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 external fixation, have some risks.



Some risks to be aware of and ask questions about if you have any concerns include:

- Anesthetic complications — most common are nausea and vomiting.
- Infection — most common is pin-site infection, which can typically be treated with antibiotics (although more intensive treatments may be necessary in some cases).
- Nerve problems — may occur, but are rare.
- Blood vessel problems — may occur, but are rare and more often due to immobility rather than the fixator or procedure themselves.
- Joint or muscle problems — muscle stiffness is common, and can be managed by walking and doing exercises according to your surgeon's instructions.
- Wire or pin breakage — in the occasional event of breakage, the wire or pin may be repaired, removed and replaced.
- Blood clots in the leg, which may result in thromboembolic disease (blood clots in the lungs) — this can be a complication of any operation. The surgeon and the hospital

should have a protocol for avoiding this problem and this should be explained to you.

- The bone may break if it is not healed properly (fracture), or it may be slow to heal or fail to heal (delayed or nonunion). Any operation involving a bone osteotomy may develop these problems, and your surgeon can explain how much the risk is in your case.
- At the end of treatment, the deformity or the original problem may not be completely cured and you may still have some symptoms. Again discuss with your surgeon.

Your surgeon will give you information on these occurrences, including the symptoms that should prompt you to seek treatment, as well as the appropriate healthcare professional to contact.

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. Alternately, you and your surgeon can 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 external fixator will be in place depends on the severity of the deformity, and how much correction is needed, as well as your/your loved one's 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/your loved one's specific situation.

You should prepare your home in advance of the surgery. For example, getting on and off the toilet might cause you problems if your fixator extends on to the thigh, so it's a good idea to get raised toilet seating that accommodates the fixator. You may also need aids to make getting in and out of the bath safer and easier.

Other devices that may come in handy include long-handled sponges and shoe-horns, long-handled graspers (for items on high shelves), and long-handled sock aids. Because standing ability may be reduced during recovery, a high stool to sit on may be helpful to have in both the kitchen and bathroom, for carrying out daily activities. It might be helpful to have in both the kitchen and bathroom, for carrying out daily activities.

Your physician, or the care team, will estimate the duration of your hospital stay and will indicate what you should bring with you for the hospitalization

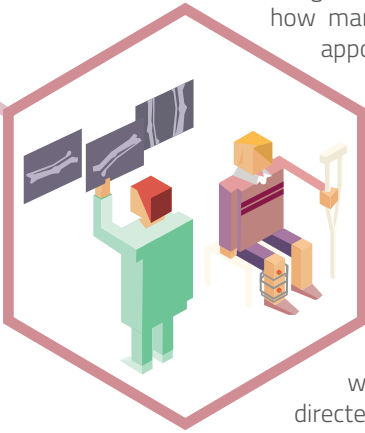


CARE AFTER SURGERY

Living with your fixator

For however long you wear it, your fixator should provide firm but comfortable control. During your treatment, there may be some modifications to the things that you can do, but you should find that the fixator does not interfere too much with your normal life. As soon as your fixator is no longer needed, it can be removed quickly and easily, probably in an out-patient setting.

Your surgeon will explain the schedule for adjustments, and how many visits will be needed. Be sure to plan these appointments in advance, taking in consideration transportation issues.



Before you are discharged from hospital you will receive information about weight bearing and mobility. You may require a wheelchair or crutches, depending on the treatment you have had. 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 more able to bear your full weight, if directed by your treating physician.

Pain Relief

You/your loved one 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/your loved one 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 or family doctor. As the pain decreases, you can eventually stop taking the painkillers.

Pin-site care

You/your loved one will be taught how to clean the pin sites — that is, the area of skin around the pin or wire, where it passes through the skin.

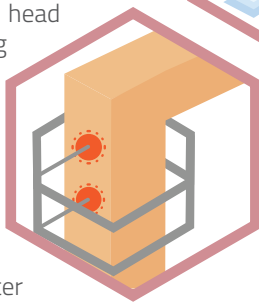
You can clean the fixator frame with a damp cloth or cotton buds to keep the whole fixator free of dust, grease or dirt. If you are able to shower, you may clean the fixator gently with soap and water, drying it afterwards with a clean towel.

If you/your loved one have taken a bath, rinse the frame and pin sites with the shower head afterwards, proceeding with cleansing solution if instructed to do so.

All pin sites need to be checked every day, according to the instructions for pin site care in the brochure and/

or video provided by your surgeon or hospital staff after surgery.

If the pin site becomes “clogged” from leakage that has dried, the site will need to be cleaned.



Follow exactly the instructions for pin site care in the brochure and/or video provided by your surgeon or hospital staff after surgery

Exercises and Physiotherapy

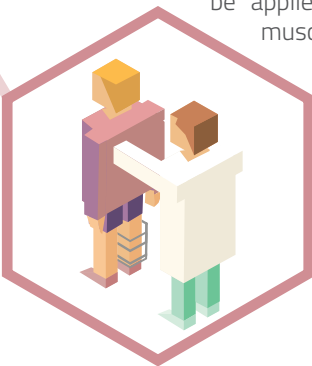
Exercises will be taught to you/your loved one by a physical therapist.

If you do not do these exercises, you could have permanent joint stiffness, or it may be necessary for your surgeon to stop the deformity-correction process, to let the limb recover. This could mean you have to wear the external fixator for a longer time. Your family, friends or a caregiver can also be taught the exercises, to help you/your loved one in doing them.

Physical therapy exercises should be performed according to the instructions of hospital staff or a physical therapist. Doing them will help strengthen your/your loved one's muscles, joints and bones, and prevent stiffness and shortening. One of the reasons external fixation works well is that the normal body stresses on the skeleton continue to be applied through the skeleton and muscles, while the fixator device safely holds

the limb. Following physical therapy instructions, it is extremely important to make sure you/your loved one gain the maximum benefits of surgery and external fixation. Bear in mind that excessive exercise may also be harmful. Always follow the physical therapist's instructions.

Following physical therapy instructions, it is extremely important to make sure you/your loved one gain the maximum benefits of surgery and external fixation



Adjustments to the Fixator

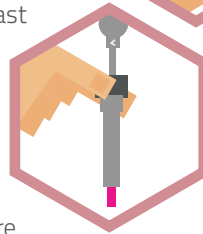
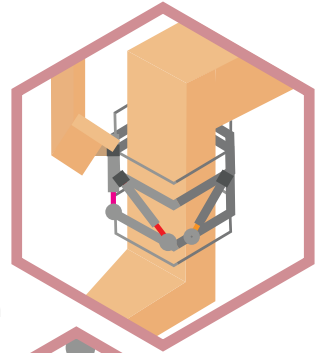
Soon after your surgery, you will be shown how to adjust the length of your fixator frame. The number of times a day you need to do this will be decided by your surgeon. This lengthens your bone at a comfortable rate set by the surgeon, letting your new bone cells grow. Lengthening too fast may mean

that new bone cannot grow fast

enough and this will cause problems with bone healing. Lengthening too slowly may

result in the bone growing together before lengthening is done.

By taking regular X-ray or ultrasound pictures of your bones, your doctor will make sure that the adjustments aren't happening either too fast or too slowly, and may ask you to change the rate of adjustments as a result. Even when your leg reaches the right length and angle, you/your loved one will still wear the fixator while the bone grows strong. You/your loved one may need to wear a cast for a short while after the fixator frame has been removed.



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 the bone growing together before lengthening is done.

Coping your ups and downs

Your physician and the care team have recommended this type of treatment for your limb also because they believe that you are ready and have the resources to face this journey. Despite this, along the way you may experience difficulties dealing with the pain or your limitations on daily activities.

Remember that you play a core role for the success of your treatment. Do not hesitate to call for help when you feel you cannot cope with such difficulties. You will wear the device only for a limited part of your life: remind yourself why you decided to start this journey.

Try to maintain as many daily routines as possible and continue attending social activities. As a good suggestion, before starting this journey prepare a personal list of activities that you like to do (meeting friends, going to the movies, reading books, listening to music...), so that you can refer to this list in the upcoming months.

If not already part of the care team, check with your physician if a psychological service is available in the hospital structure, and seek for counselling if and when needed.

Shower

Your physician may allow you to shower with your external fixator approximately 10 days post surgery. While in the shower, gently clean your external fixator. Afterwards, dry the fixator thoroughly with a clean towel. Please pay attention not to alter the different elements of the fixator.

Potential complications

Even with excellent pin-site care, there is a chance that pin sites may become infected or cause complications. It is possible that you might see one or more of the following symptoms of infection:

- Redness at the pin site
- Swelling at the pin site
- Thick or colored discharge from the pin site
- Loosening or movement of the pin
- Persistent pain or soreness at the pin site

If you experience any of these signs or if you have doubts on the pin site cleaning procedure, you should contact your surgeon's office immediately.

If your surgeon has prescribed antibiotics to ward off possible infection, be sure to take them as prescribed until all the medication is used. Remember to clean your pin sites daily even if you are taking an antibiotic.

Your surgeon will provide you with information on other potential post-operative complications, including the symptoms that should prompt you to seek treatment, as well as the appropriate healthcare professional to contact



Clothing

You may need to buy clothing a few sizes bigger than usual or track pants with buttons or zips on the outside of the leg, to accommodate the external fixation device. Long skirts may be useful. To help keep warm, you may want to purchase or make a tube of material (for example, from an old sweatshirt or sweatpants) as a “leg-warmer.” For ankle frames, there are special “boots” that are adjusted to fit the frame and allow walking. You may also use material to create foot-warmers in these cases.

Sleeping

You may need to make adjustments to your/your loved one’s sleeping position while the fixator is in place. Ask your surgeon’s office or your physical therapist for advice on accommodating the fixator in bed.

Other medications

Refer to your physician to understand if you can continue to take your regularly prescribed or over-the-counter medications after the external fixation 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

Children should mobilize 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. Pictures of the external fixator may be useful to bring along to this meeting.

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, and to get a letter from your surgeon in order to pass through security at the airport with the fixator in place, or with medicines related to the surgery.