

PATIENT INFORMATION

Eight-Plate

Guided Growth System+™

**Gentle Guided Growth
to Correct Knock Knees
and Bowed Legs
in Children**

Not an actual patient

 **ORTHOFIX®**
ORTHOPEDICS

Introduction

Children need gentle guidance and correction in many aspects of their lives. For a significant number of children who do not spontaneously grow out of “bowed legs” or “knock knees”, pain and/or difficulty in running may ensue. These children may benefit from a minimally invasive surgical procedure that involves the insertion of a small device called the *eight-Plate Guided Growth System™* and *eight-Plate Guided Growth System +™* (*eight-Plate System* and *eight-Plate Plus System*). These two systems gently guide growth while allowing natural, safe and gradual correction of limb alignment.

Growing up is tough enough on both children and their parents! Using either the eight-Plate System and eight-Plate Plus System, your surgeon can accurately and selectively correct limb deformities so that your child can get on with growing up *strong* and *straight*.

Read on for more information about the correction of limb deformities using the eight-Plate System or eight-Plate Plus System and a procedure referred to as hemi-epiphysiodesis.

Knock Knees and Bowed Legs

In normal skeletal growth, limbs are equal in length and are properly aligned from the hips to the ankles. Sometimes, however, congenital abnormalities, infection, injury or other conditions can cause long bones of the leg (e.g., tibia, femur) to grow out of alignment.

This misalignment often may result in joint deformities of the leg known as valgus (knock knees) or varus (bowed legs) deformities. In these situations, normal use of the leg is impaired and walking or running may be painful.

Unfortunately, bracing is not effective in the management of these conditions. The correction of limb deformities requires one of two surgical procedures: either an osteotomy [os-te-ot-o-me] or the minimally invasive hemi-epiphysiodesis [hemi-ep-i-fiz-e-o-de-sis].

Corrective Surgical Procedures

Correction using the osteotomy method is a significant surgical procedure that involves cutting the misaligned bone, adding or removing a wedge of bone (depending on the type of deformity) and realigning the bone. The realigned bone must be fixed into place with pins or with a plate and screw combination followed by a cast.

Another alternative is to fix the realigned bone in place using pins in the bone segments and connecting them to an external frame. In addition to the inherent risks of such a surgery, the child must endure a prolonged hospital stay and delayed weight bearing, followed by a course of physical therapy. In many cases, multiple osteotomy surgeries may be necessary to fully correct the leg's alignment. In contrast, hemi-epiphysiodesis is a much less invasive surgical method for correcting pathological angular deformities.



Epiphysiodesis

An operation to stop the activity of a growth plate. The effects can be permanent or temporary

Hemi-epiphysiodesis

To tether or restrain one side (medial or lateral) of the growth plate with an implant

Femur

The long bone of the thigh

Tibia

The larger leg bone between the knee and ankle (shin)

Normal alignment

Younger children should be able to stand with the knees and ankles touching simultaneously

Valgus

An inward angulation of the knee in which the ankles are separated while the knees are touching; "knock knees"

Varus

An outward angulation of the knee in which the knees are separated while the ankles are touching; "bowed legs"

Osteotomy

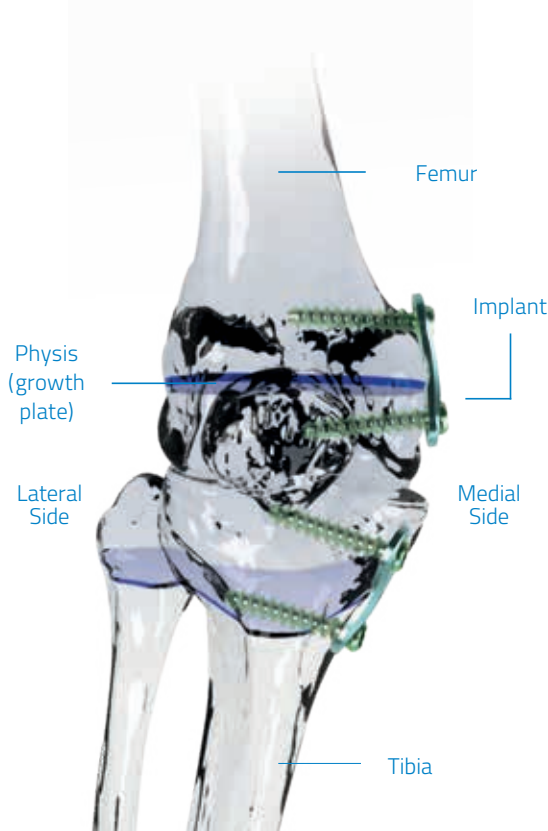
Cutting a bone into two segments

Epiphysiodesis is a Greek term in which “physis” means growth plate and “desis” means tether.

This procedure, traditionally known as “epiphyseal stapling” utilizes surgical staples (typically 2 or 3) on one side of the physis, restricting its growth while permitting continued growth on the opposite, non-instrumented side.

The goal is to permit realignment through growth. Bone growth is restricted on one side of the deformity while bone growth continues on the other side. Gradually, the bone realigns and the deformity is corrected. Since the bone is not cut (as with an osteotomy), there is no neurovascular risk, instability from the cut, or significant period of healing.

Despite the fact that epiphyseal stapling has been used with success for more than 50 years, there are drawbacks and limitations to the use of staples. Staples are rigid, U-shaped implants that allow no flexibility during the growth and realignment of the bone. Additionally, the staples compress the growth

**Physis**

Growth plate near either end of the long bones (femur and tibia) that allows for elongation. These close naturally at skeletal maturity (indicatively, girls at age 14, boys at age 16 approximately)

Medial

Inner side near the midline

Lateral

Outer side, away from the middle or median plane

Implant

Device inserted into a tissue for a specified period of time that is not absorbed by the body

plate on one side. Surgical planning for the precise placement of the staples is complicated. Furthermore, when rigid implants such as staples are confronted by the powerful forces generated by physis (growth), the staples may migrate, bend or break and compromise the outcome. Staple retrieval or revision may prove difficult, resulting in inadequate correction (or overcorrection) of the deformity.

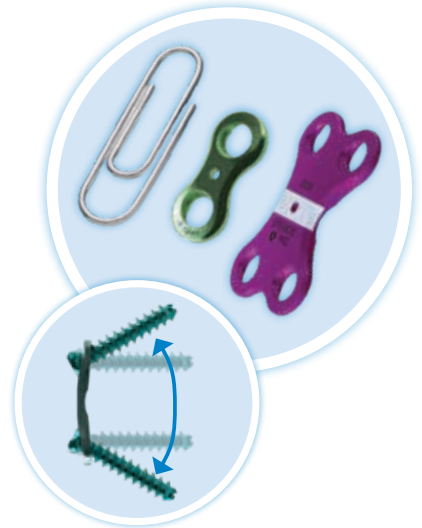
Correction Through Guided Growth Using the eight-Plate Plus System

The eight-Plate System and eight-Plate Plus System technique of guided growth overcomes the drawbacks associated with traditional stapling and may give your child improved correction of their pathological angular deformity.

The eight-Plate Plus System is a unique, figure-eight shaped device about the size of a paper clip, which allows gradual correction of your child's limb deformity.

The eight-Plate Plus System holds one side of the growth plate. As the opposite side of the physis continues to expand and grow, the screws diverge within the plate, effectively serving as a hinge. This hinge action avoids compressing the growth plate that is being guided. And because of its flexibility, the chances of the plate or screws bending or breaking under the forces of bone growth are considered very low.

(data on file)



The Surgical Procedure

Implantation of the eight-Plate System and eight-Plate Plus System is performed under anesthesia and takes generally about an hour. During the procedure, the surgeon will make a 2–3 cm (approximately 1") incision at the physis of the bone to be corrected. The eight-Plate or eight-Plate Plus is secured to the bone with two small screws.

For “knock knees” the eight-Plate System or eight-Plate Plus System is placed on the medial side of the bone (i.e., inner side); for bowed legs, the eight-Plate or eight-Plate Plus is placed on the lateral side of the bone (i.e., outer side). Multiple deformities can be addressed during the same procedure, inserting one eight-Plate System or eight-Plate Plus System per physis. The incision is closed, generally with resorbable sutures. After recovery from anesthesia, your child may be taken home.

Postoperative Recovery

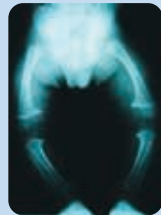
The eight-Plate System or eight-Plate Plus System technique of guided growth involves minimal surgical trauma and pain when compared to an osteotomy. Although ultimately your surgeon will provide details on your child’s specific case, a cast is generally not required and crutches are usually optional (for comfort).



Trevan’s Story

At the age of 2 Trevan was diagnosed with a hereditary condition that made his legs bow out and he walked with a waddling gait. Activities caused him hip and knee pain. He received treatment with the eight-Plate System and at one year, his legs had straightened and his symptoms were resolved.

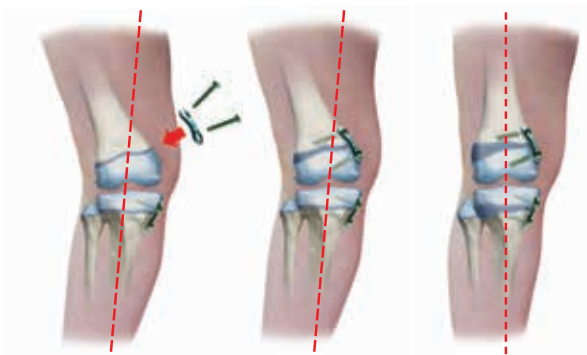
The eight-Plate System has allowed Trevan to receive treatment at an earlier age, and his deformities were corrected without major surgeries, without an osteotomy and without hospital stays or casting. He is now enjoying a normal, active childhood.



Subject to your surgeon's medical judgment, typically children are encouraged within three weeks from the surgery date to walk and resume activities as tolerated, including sports when comfort permits.

Correction Occurs Gently Over Time

The eight-Plate System and eight-Plate Plus System temporarily restrain growth on one side of the bone plate while natural growth is allowed to continue on the opposite side. Gradually over time, (typically from several months up to one year) the deformity is corrected. To ensure timely and adequate correction, your child needs to be seen by the surgeon every three months for a check-up or as recommended by your surgeon. If your child cannot return to the surgeon every three months, please follow up with your surgeon to plan an alternative means of monitoring your child's correction. This may involve locating another doctor to take x-rays of the legs (the most accurate film is a full length view taken in the standing position) and sending these x-rays to the surgeon who implanted the eight-Plate System or eight-Plate Plus System. When the deformity is corrected, the surgeon will remove the eight-Plate System or eight-Plate Plus System under anesthesia in an outpatient surgery.



at time of surgery



several months up to one year

Sometimes, our children need a little extra correction. And if that correction is needed for a joint deformity, rest assured that you and your child are not alone. We understand that surgery on our little ones is traumatic for you and the child, but consistent correction and gratifying clinical results have been achieved with guided growth using the eight-Plate System or eight-Plate Plus System.

WITH LEG LENGTH DISCREPANCIES,
BOTH SIDES OF THE GROWTH PLATE
ON THE LONGER LEG ARE BLOCKED
USING THE EIGHT-PLATE PLUS SYSTEM.

MULTIPLE ALIGNMENT ISSUES
CAN BE CORRECTED
AT THE SAME TIME.



Advantages for your child

FEATURES AND BENEFITS

- Dedicated for redirecting the growth of long bones in growing children
- Color coded plates and screws
- Sterile and non-sterile implants
- Eight-Plate (for two screws) and quad-Plate (for four screws)
- Unique screw hole design for a screw angulation up to 60 degrees

SURGEONS BENEFITS

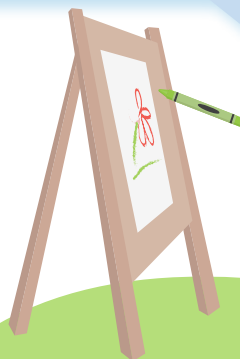
- Plate sizes: 12, 16 and 20mm
- Cannulated and solid screw options
- Titanium alloy implants
- Optimized and lean instrumentation
- Central “dome” designed to aid application and removal across the growth plate

PATIENTS BENEFITS

- Minimally invasive
- Early weight bearing as tolerated by the patient and under surgeon discretion
- Titanium alloy implants to avoid allergic reaction to nickel
- Low profile plates

I'M NOT ALLOWED TO EAT ANYTHING
BEFORE THE OPERATION.

MY PARENTS CAN COME WITH ME
UNTIL I GET ANESTHESIA, OR UNTIL I'M
JUST OUTSIDE THE OPERATION ROOM.



PARENTS AND CHILD SEE EACH OTHER
AGAIN IN THE RECOVERY ROOM.

THE CHILD CAN PUT WEIGHT ON THE LEG
IMMEDIATELY AFTER SURGERY,
AS TOLERATED BY THE PATIENT AND
UNDER SURGEON DISCRETION.

PLASTER CASTS ARE NOT NECESSARY.
HOWEVER, THE CHILD IS NOT ALLOWED
TO PRACTICE SPORTS RIGHT AWAY.



PACKING LIST

FOR YOUR SHORT STAY AT THE HOSPITAL

- ☐ Insurance card, if applicable for patients with public insurance, depending on the Country you reside
- ☐ Clinic card, if applicable for patients with private insurance, depending on the Country you reside
- ☐ If applicable Doctor's referral form
- ☐ The surgeon should already have this information by the time surgery is scheduled
- ☐ Medical IDs, if any: allergy pass, x-ray pass, diabetic ID, etc
- ☐ Prescriptions and over the counter medications
- ☐ Current X-rays, for example on a digital storage device
- ☐ Current medical reports
- ☐ Current laboratory results
- ☐ Dialysis patients: please bring your dialysis medications with you
- ☐ Pajamas
- ☐ Comfortable flat shoes
- ☐ Warm socks
- ☐ Bathrobe, loose, comfortable casual clothes
- ☐ Toiletries (toothbrush, soap, lotion, etc.)
- ☐ Child's favorite pillow
- ☐ Favorite stuffed animal, a toy or two
- ☐ Device to play music or watch videos and headphones
- ☐ -----
- ☐ -----





We understand that the decision to have surgery for a child is a big one. Our goal is to provide the information, support, and resources that will help children, teenagers and parents make informed decisions about pediatric conditions, injury prevention, and treatment.

Please visit www.OrthofixKids.com



About Orthofix

For more than 40 years, our medical devices have been used to help children around the world.

The Orthofix team researches, designs, and produces many of the leading orthopedic treatment options available globally and provides the support and information that everyone involved in the surgery and healing process needs.

Frequently Asked Questions

Question: Is the eight-Plate System or eight-Plate Plus System meant to be permanent?

Answer: No, it should be removed when the deformity is corrected.

Question: How long can the eight-Plate System or eight-Plate Plus System safely be left in place?

Answer: As long as it is required, pending correction of the deformity. The typical range is 6–18 months.

Question: What are the indications for eight-Plate System or eight-Plate Plus System application?

Answer: Any angular deformity of the femur or tibia that would otherwise warrant an osteotomy in a patient with open growth plates, or any length discrepancy that would otherwise merit epiphysiodesis.

Question: Is a cast required after eight-Plate System or eight-Plate Plus System application?

Answer: No cast is generally required.

Question: Can the patient go home on the day of surgery?

Answer: Yes, generally patients go home after surgery on the same day.

Question: Are there any limitations or precautions in terms of weight-bearing?

Answer: Typically patients are encouraged to carry out immediate weight-bearing activities and early motion as advised by their doctor.

Question: How often does the patient have to come back for a check-up?

Answer: Patients should be seen at least every three months to monitor their growth and determine when to remove the plate.

Question: Are there any contraindications to the eight-Plate System or eight-Plate Plus System?

Answer: The eight-Plate System or eight-Plate Plus System should not be used for adult deformities (when the growth plates have closed) or where the growth plate has closed, such as due to trauma or infection.

Question: What is the recommended age and/or size for a patient to have an eight-Plate System or eight-Plate Plus System implant?

Answer: Since the eight-Plate System or eight-Plate Plus System does not bear any body weight after it is implanted, patient size really doesn't matter. The eight-Plate System or eight-Plate Plus System can be used successfully in patients as young as 18 months or as old as 17 years, as long as the child is still growing (skeletally immature). Proper patient selection and the patient's ability to comply with physician instructions and follow the prescribed treatment regimen will greatly affect the results. It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations.

Question: Is the use of the eight-Plate System or eight-Plate Plus System limited to knock knees and bowed legs?

Answer: No, it may be used to correct other angular deformities such as flexion or extension deformities of the knee; valgus, extension or flexion deformities of the ankle.

Electronic Instructions for use available at the website <http://ifu.orthofix.it>

Electronic Instructions for use - Minimum requirements for consultation:

- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):

tel +39 045 6719301, fax +39 045 6719370,

e-mail: customerservice@orthofix.it

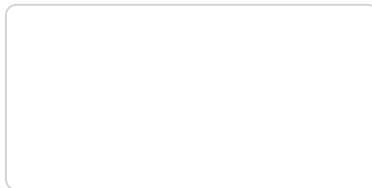
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Proper surgical procedure is the responsibility of the medical professional. This Manual is 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 product Instructions For Use supplied with the products for specific information on indications for use, contraindications, warnings, precautions, adverse effects and sterilization.



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Illustrations designed by Freepik

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EP-0601-PL-E0 G 04/23

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