

PATIENT AND FAMILY GUIDE

MAGEC[®]

**NONINVASIVE
GROWTH
MODULATION**

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INTRODUCTION

What Is Scoliosis?

Anatomy:

Viewed from the front or back, the spinal column should be straight. When scoliosis is present, you will see a sideways bending or curvature of the spine to the right or left. The spinal curve is diagnosed using an x-ray image, and the curve of the spine is measured in degrees, referred to as a Cobb angle. Scoliosis is defined as an abnormal curvature of the spine with a Cobb angle greater than 10 degrees.

Who is affected?

- Approximately 10% of the population has small curves (less than 10 degrees) which are of no consequence to function or health.
- About 1 in 1,000 people have scoliosis that requires medical observation or attention.

What Causes Scoliosis?

Scoliosis can arise from a number of underlying conditions.

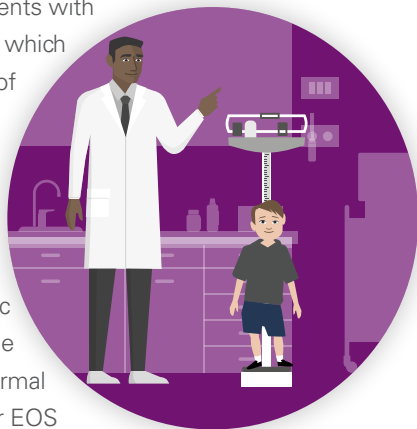
Doctors don't know what causes the most common type of scoliosis — idiopathic, meaning "of unknown origin." Idiopathic scoliosis does appear to involve hereditary factors, because the disorder has been shown to run in families. Other types of scoliosis may be caused by:

- Neuromuscular conditions, such as cerebral palsy or muscular dystrophy;
- Birth defects affecting the development of the bones of the spine;
- Injuries to or infections of the spine;
- Underlying syndromes.



WHAT IS EARLY ONSET SCOLIOSIS?

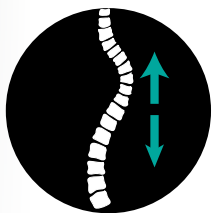
Early onset scoliosis (EOS) affects **skeletally immature** patients less than 10 years of age. Patients with EOS are still undergoing development, which can place them at risk for progression of the deformity. Many children can be treated through observation or the use of an external, wearable brace. If EOS progresses to a severe state, the spine can crowd the space within the chest cavity, and can cause Thoracic Insufficiency Syndrome (TIS), where the chest cavity (thorax) cannot support normal breathing or lung growth. Treatment for EOS should be sought in a timely manner to prevent progression of the deformity.



Treatment Goals

The treatment goals for EOS are:

- Controlling progression of the deformity,
- Growth of the chest cavity space by increasing the height of the thoracic spine.



Surgical treatment for patients is focused around preserving the general mobility of the spine, so these patients do not undergo the same correction and fusion procedure that adolescent idiopathic scoliosis (AIS) patients do.

Options Available for Treatment

Minor to moderate cases of EOS can be treated through **observation, casting, or bracing**.

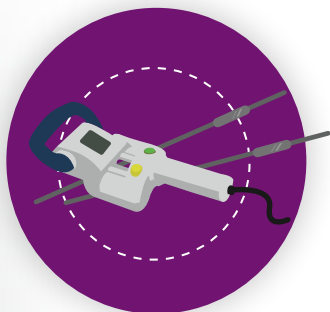
The traditional surgical treatment for patients with moderate to severe cases of EOS requires an initial surgery (typically between ages 5-7), where rods are implanted to gain control of the deformity. Many treatment options are “growth-friendly,” and most utilize **“growing rods”** that can be distracted (lengthened) as the child grows. Following implantation of growing rod(s), patients will undergo a planned distraction surgery every six months, allowing for continued growth during treatment. Sometimes these distraction surgeries can add up to an additional 14 procedures beyond the initial surgery.



Distraction surgeries required for growth throughout treatment have some observed downsides:

- Additional cost to families for treatment⁶
- Increased chance of postoperative infections³
- Increased risk of psychological distress and anxiety due to repetitive and prolonged time in the hospital
- Repetitive exposure to x-rays
- Repetitive exposure to anesthesia when brain development is at risk of being affected¹
- Additional social, economic, and health-related complications for patients and families^{3,5,6}

THE MAGEC® SYSTEM: A NOVEL APPROACH TO EOS TREATMENT



NuVasive®, along with thought leaders in pediatric spinal deformity, recognized the need for an alternative form of EOS treatment – the MAGEC system.

MAGEC eliminates the need for a series of invasive surgeries, while still allowing patient growth throughout treatment.

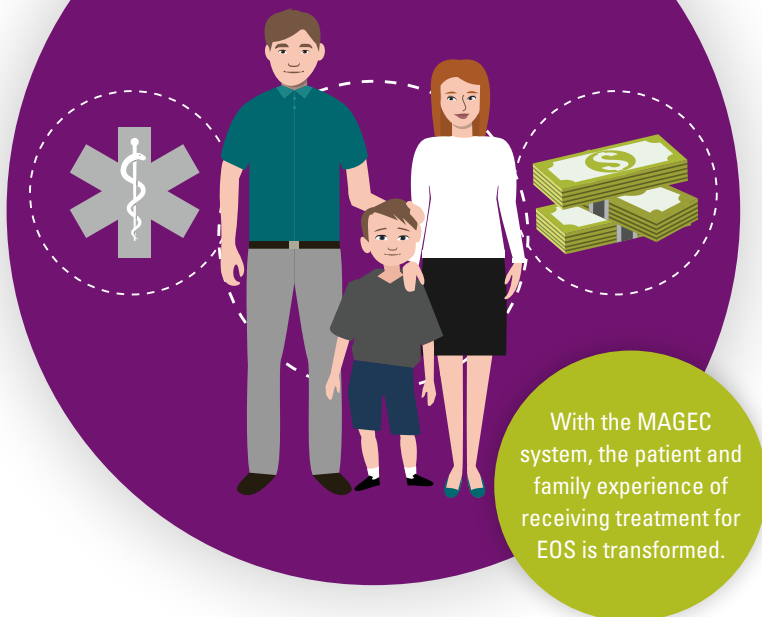
Noninvasive Growth Modulation

The MAGEC system allows EOS patients to undergo the same growing rod treatment as traditional approaches, but through noninvasive distractions. Planned distractions take place in an office setting, typically at the cost of a regular office visit. These noninvasive distractions are generally quick and painless, and the child can return to activity immediately after the office visit (per the doctor's guidance on acceptable activities).

The doctor will decide when the patient has matured enough to remove the MAGEC rods.



MAGEC®



Benefits of noninvasive distractions:

- Reduced number of overall surgical procedures⁴
- Reduced frequency of exposure to anesthesia¹
- May limit chances of acquiring infections⁶
- Avoidance of multi-day stays in the hospital every six months
- May prevent the repetitive anxiety associated with these distractions³
- Lower overall cost of treatment when compared to a surgical distraction procedure used for traditional growing rods⁵

THE MAGEC® SYSTEM: A NOVEL APPROACH TO EOS TREATMENT

Explanation of the Technology

The MAGEC system includes:

- A titanium **adjustable growing rod** that is surgically implanted and secured using spinal fixation components, such as pedicle screws, hooks, and/or connectors;
- A handheld **External Remote Controller (ERC)** that is used at various times after implantation to distract the implanted MAGEC rod from outside of the body.



The MAGEC rod braces the spine during growth to minimize the progression of scoliosis. The rod includes a magnet which allows the rod to be adjusted by the ERC.

In an office visit, the ERC is held over the child's spine and activated. Magnets within the ERC cause a magnet in the rod to rotate, and the MAGEC rod is lengthened or shortened as controlled by the doctor.

The rod distractions allow the doctor to drive or follow natural patient growth until he/she deems the MAGEC rod has achieved its intended use. At this point, the MAGEC rod will be explanted.



The MAGEC® system is comprised of the following technology:



**External
Remote
Controller
(ERC)**

The MAGEC ERC controls the magnet within the MAGEC rod and, when activated, can lengthen or shorten the MAGEC rod within the patient. The ERC is placed over the patient's skin, providing noninvasive growth modulation.

The MAGEC rod is implanted into the child's spine to act as an internal brace to prevent the progression of scoliosis, while allowing for continued growth of the spine of the child. The rod is lengthened through a noninvasive procedure in an office setting.



**MAGEC
Rod**



**MAGEC
Manual
Distractor**

The MAGEC Manual Distractor is used to verify MAGEC rod functionality before implantation into the spine.

The MAGEC Wand is used to locate the magnet within the MAGEC rod during the distraction office visit. This allows for optimized adjustment control with the ERC.

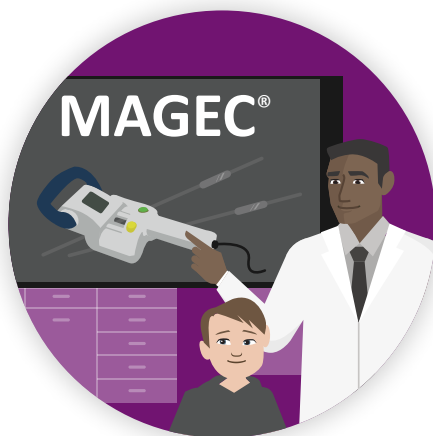


**MAGEC
Wand**

BEFORE MAGEC® SURGERY

What Should Be Done Before the Surgery?

Your child's doctor will discuss with you the different ways to treat EOS, including the MAGEC system and other alternative therapies. The doctor will also talk to you about your child's exact condition and needs, as well as the risks and benefits of having a spinal growth rod. Discuss your child's medical history and/or current conditions with the doctor before deciding on a treatment plan.



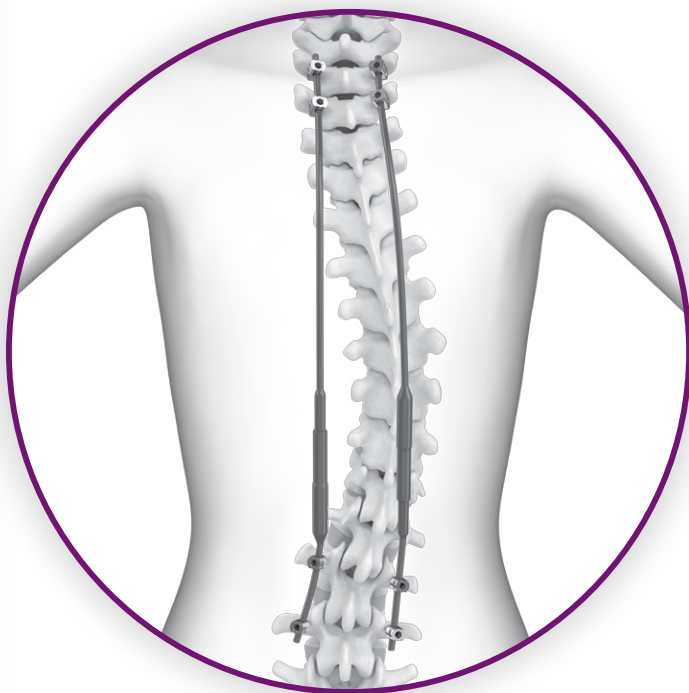
If you decide MAGEC is the right treatment for your child, you will work with your doctor to schedule a date for surgery. The doctor will provide all information needed to get your child ready for the surgery. The doctor will also talk to you about the limitations your child may experience and cautions to be aware of once the MAGEC rod has been implanted.

X-ray images will be taken of your child prior to surgery for baseline measurements.

What Happens During the Surgery?

During your child's surgery, the doctor will make two small incisions at the planned foundation sites for the MAGEC rod(s). Anchors will be connected to the spine at the planned foundation sites. The MAGEC rod will be cut and bent to the desired shape, and inserted under the skin between each foundation site. The spine will be distracted along the rod to the desired amount, and the rod will be secured to the anchors at the foundation sites.

If your child is having a revision procedure, the MAGEC rod may be secured to instrumentation already implanted.



AFTER MAGEC® SURGERY

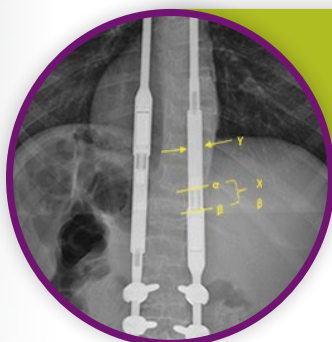
What Happens After the Surgery?

Always follow the postoperative instructions provided by the doctor.

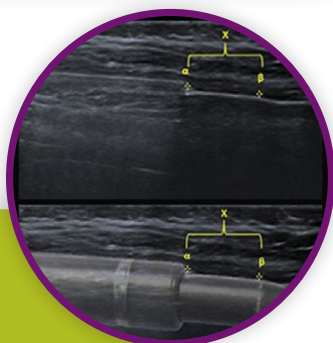
After surgery, noninvasive distractions of the MAGEC rod(s) will be required to keep the length in line with your child's growth. The postoperative treatment plan will include how often your child should return to the doctor's office for these distractions.

At these visits, your child will lie in a prone position (lying face down), and the MAGEC Wand will be used to locate the magnet within the implant. The MAGEC External Remote Controller (ERC) will be turned on, and then placed over this location. There are magnets within the ERC that, when activated, rotate and cause the magnet within the implanted MAGEC rod to rotate as well. This drives the lengthening, or distraction, of the rod.

The doctor is trained on the distraction process, and knows how long to use the ERC on your child. X-ray or ultrasound images will be taken before and after the distractions to record the changes in measurements.



An x-ray image of a child implanted with the MAGEC rod after multiple distraction visits. "X" indicates the total amount of postoperative distraction.



An ultrasound of the same patient, where "x" indicates the total amount of postoperative distraction.

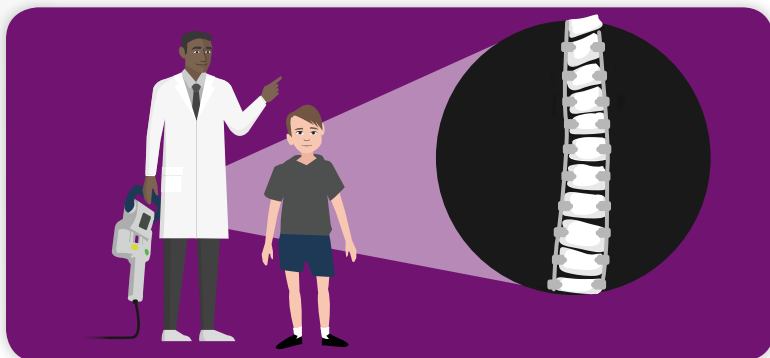
How Often Will My Child Need Distracting?

The treatment plan is specific to your child's condition. Patients can expect to have distractions every three months (on average) until your doctor deems the treatment complete. The distraction results will be checked with x-ray or ultrasound technology. Discuss any risks associated with repetitive x-ray exposure with your doctor. Based on distraction results, your child's treatment plan may be adjusted.



What Happens During My Child's Growth?

As your child grows, the MAGEC rod(s) will be distracted to slowly correct the curve in the spine, and increase thoracic spine height. When your child has reached the maximum distraction allowed by the implant, or when the doctor deems him/her as skeletally mature, the MAGEC rod(s) can be removed. At that point, the doctor may recommend a final fusion procedure to correct the remaining deformity.



AFTER MAGEC® SURGERY

What Are the Lifestyle Changes My Child May Experience?

Your child's activities will be limited following surgery, and you will need to remind him/her to avoid putting excessive weight and stress on the back during the entire treatment and as instructed by the doctor. Too much activity and weight/stress on your child's back may cause the implant to break. For the entire time your child is implanted with the MAGEC rod, sports and extracurricular activities are not recommended until cleared by the doctor.

When Should I Contact My Child's Doctor?

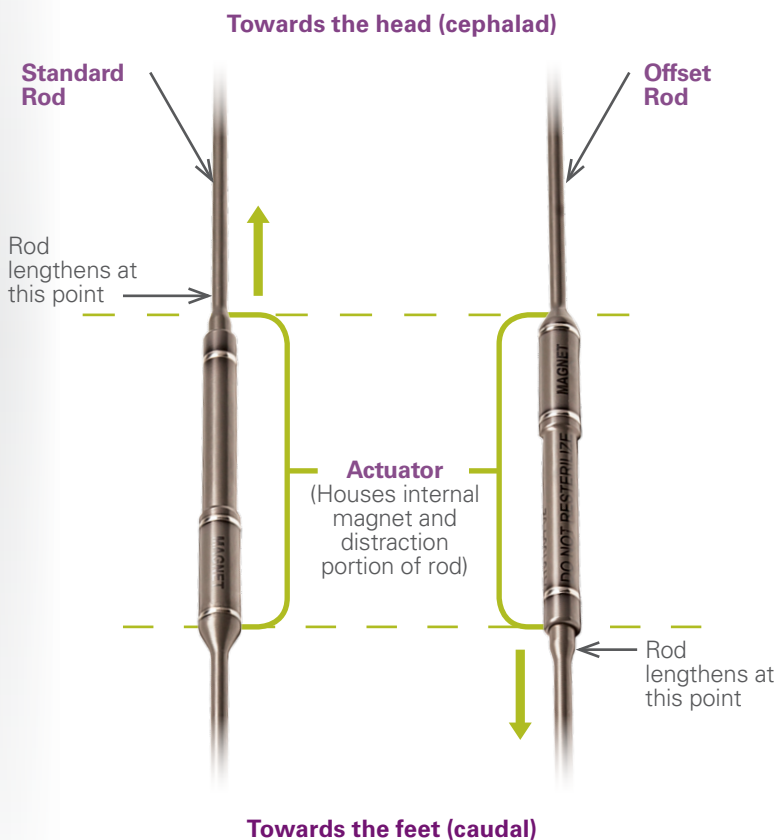
If your child feels any abnormal pain or you notice any changes in the skin around the implant, the implant may have broken or loosened. You should contact your child's doctor immediately in this case. Discuss any pain and discomfort your child is having with the doctor during the follow-up visits.



A CLOSER LOOK AT THE MAGEC® ROD

One or two MAGEC rods can be implanted into the patient. When two rods are used, two rod types are available with different actuator sizes and diameters:

- **Standard Rod**
- **Offset Rod**

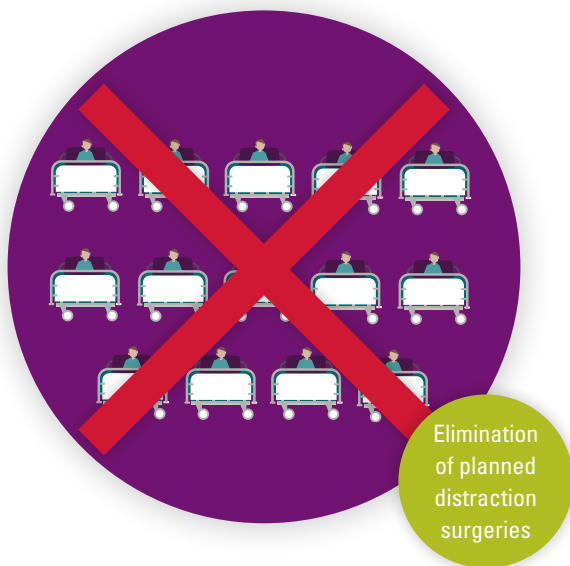


CLINICAL BENEFITS OF THE MAGEC® SYSTEM

Expected Benefits

Some of the probable benefits to patients with the MAGEC implant include the following:

- Correction of the curvature of the spine, measured by the Cobb angle;
- Increase in thoracic spine height;
- Improved space available for lung growth;
- An overall healthy weight gain;
- Improved coronal and sagittal alignment of the spine;
- Noninvasive lengthening of the MAGEC rod, using an External Remote Controller without the need for multiple surgeries to lengthen the rod;
- A reduced adverse event profile when compared to traditional growing rods.



Literature References

MAGEC helps reduce patient exposure to anesthesia and helps increase postoperative pulmonary function.

¹Yoon WW, Sedra F, Shah S, et al. Improvement of pulmonary function in children with early-onset scoliosis using magnetic growth rods. *Spine* 2014;39(15):1196-202.

MAGEC helps reduce radiation exposure for patients.

²Stokes OM, O'Donovan EJ, Samartzis D, et al. Reducing radiation exposure in early-onset scoliosis surgery patients: novel use of ultrasonography to measure lengthening in magnetically-controlled growing rods. *Spine J* 2014;14(10):2397-404.

MAGEC helps minimize psychological distress and improve quality of life for patients during treatment.

³Cheung KM, Cheung JP, Samartzis D, et al. Magnetically controlled growing rods for severe spinal curvature in young children: a prospective case series. *Lancet* 2012;379(9830):1967-74.

MAGEC patients undergo significantly fewer surgical procedures than traditional growing rod patients.

⁴Akbarnia BA, Pawelek JB, Cheung KM, et al. Traditional growing rods versus magnetically controlled growing rods for the surgical treatment of early-onset scoliosis: a case-matched 2-year study. *Spine Deformity* 2014;2(6):493-97.

MAGEC rods achieve cost neutrality with traditional growing rods at 3 years, and provide cost savings thereafter.

⁵Su AW, Milbrandt TA, Larson AN. Magnetic expansion control system achieves cost savings compared to traditional growth rods: an economic analysis model. *Spine* 2015;40(23):1851-6.

⁶Bess S, Akbarnia BA, Thompson GH, et al. Complications of growing-rod treatment for early-onset scoliosis: analysis of one hundred and forty patients. *J Bone Joint Surg Am* 2010 Nov 3;92(15):2533-43. doi: 10.2106/JBJS.I.01471. Epub 2010 Oct 1.

WHAT ARE THE RISKS OF USING MAGEC®?

MAGEC Indications

The MAGEC system is intended for children less than 10 years of age with severe spinal deformities associated with, or at risk of, thoracic insufficiency syndrome (TIS). TIS is a condition in which the chest is not able to support normal breathing and lung development because of the spine deformity.

MAGEC Contraindications

There are certain conditions your child may have under which MAGEC should not be used. It is important to discuss any conditions your child has with the doctor prior to deciding on MAGEC treatment. MAGEC should not be used on:

- Patients with an infection or pathologic conditions of bone which would impair the ability to securely fix the device (e.g., osteoporosis, osteopenia).
- Patients with metal allergies and sensitivities to the implant materials (e.g., titanium).
- Patients with a pacemaker or other active, electronic device (e.g., ICD).
- Patients requiring MRI imaging during the expected period that the device will be implanted.
- Patients younger than two years old.
- Patients weighing less than 25 lbs. (11.4 kg).
- Patients and/or families unwilling or incapable of following the postoperative care instructions.
- Patients with stainless steel wires or other implants containing incompatible materials.

What Are the Risks of Using MAGEC?

Surgery to implant the MAGEC rod(s) in a child is considered a major operation. All of the general risks that are linked to surgical procedures are also applicable to this surgery. Unique risks that may be associated with the use of the MAGEC system include, but are not limited to, the following:

- The MAGEC implant or fixation components can bend, loosen, not distract, move, or break as a result of daily activities, due to an accident, or during lengthening. This can be checked by taking an x-ray. If the implant breaks or is not distracting properly, the device will have to be surgically removed and a new one implanted.
- Patients with the MAGEC implant may have an allergic reaction from the implant if they have sensitivities to any of the implant materials (e.g., titanium).
- Patients with the MAGEC implant may develop worn skin due to the implants.
- Patients may develop an infection or may have a surgical wound complication.
- The MAGEC implant may cause pain or discomfort. Discuss any pain or discomfort your child may be experiencing with their doctor.
- Patients may develop pulmonary complications, junctional kyphosis, neurologic deficit(s), and coronal or sagittal imbalance.
- The MAGEC system may fail to correct the spinal deformity or support long growth. Regular doctor visits are suggested throughout treatment with the MAGEC system.

General surgical risks include problems from anesthesia, stiffness, bleeding, allergic reaction, stroke, pneumonia, heart attack, spinal cord injury, nerve root injury, cauda equina injury, blindness, dural tear, blood transfusion, deep vein thrombosis, pulmonary embolism, superficial infection, deep infection, lung failure, urinary tract infection, non-union, adjacent segment disease, persistent deformity, implant failure, death, renal failure, gastrointestinal complications, and sexual dysfunction.

What Are the Warnings for MAGEC?

- Do not let your child participate in extreme sporting activities, such as gymnastics, skateboarding, or jumping on trampolines. Metallic implants can loosen, fracture (break), corrode, migrate (move), or cause pain. You should always follow your child's doctor's instructions about how much activity your child can participate in.
- Do not let your child enter an MRI unit. The effect of the MRI unit has not been studied with respect to the implanted magnet, and is therefore unknown. This may cause harm or damage to the implant.

What Are the Precautions for MAGEC?

- Do not let your child use a brace with any metal components (steel, etc.). Using a metal brace may affect the implant, and additional distraction or surgery may be required.
- Do not let your child use a backpack that weighs more than 20 lbs. (9 kg).
- Do not have the MAGEC rod implanted in your child if he/she has a BMI (body mass index) higher than 25. The MAGEC system may not work on these patients. Your child's doctor can assess if your child's BMI is more than 25.

GLOSSARY

This section provides terms and definitions that are used throughout the MAGEC® Patient and Family Guide.

Anchor: Hooks, pedicle screws, or cross connectors that are used to create the foundation of a construct and secure the MAGEC rod in place.

Cobb Angle: The measurement used to describe the maximum coronal angle of the spine in scoliosis.

Coronal Imbalance: Imbalance of the spine between the head and the pelvis, when viewed from the front.

Distraction: Used to describe the process to lengthen the MAGEC rod, and the overall spine. The MAGEC system is used to *distract* the spine.

Early Onset Scoliosis (EOS): The term given to spinal curves greater than 10 degrees in a child diagnosed under the age of ten.

Electronic Device: This refers to any device that has a power cord, which is plugged into the wall for electrical power, or is battery-operated.

ERC: ERC stands for External Remote Controller, and is used to adjust the MAGEC rod that is implanted in the patient.

Fixation: Growing rods are connected by anchors to the vertebrae of the spine.

Foundation: At least two pairs of anchor combinations that cover from one to four vertebrae of the spine. The foundation of a construct secures the MAGEC rod.

Fusion: Surgical technique used to rigidly connect two or more vertebrae.

General Anesthesia: This refers to being put completely to sleep for a surgical procedure.

Growth Modulation: The ability to control the growth of an object or person.

GLOSSARY

Implant: A device that is inserted into the body for a period of time and is not absorbed by the body.

Junctional Kyphosis: A sagittal curvature that develops just above or below a spinal fusion level.

MRI: Magnetic resonance imaging, which is an imaging test that uses a large magnet to take images of the body.

MAGEC® Rod: The adjustable rod that will be implanted into your child's spine and is lengthened by the ERC from outside of the body.

Migration: The movement of the spinal rod and/or anchors after they have been implanted.

Neurologic Deficit: Abnormality of a body part due to decreased function of the brain, spinal cord, muscles, or nerves.

Osteopenia: A condition where bone density is lower than normal.

Osteoporosis: A condition where the bone mass and density are low and at an increased risk for fracture.

Pulmonary: Pertaining to the lungs.

Revision Surgery: A surgery required to replace existing growing rods or anchors.

Sagittal Imbalance: Imbalance of the spine between the head and the pelvis, when viewed from the side.

Scoliosis: A medical condition in which a person's spine has an abnormal curvature when viewed from the front or back.

Thoracic Insufficiency Syndrome (TIS): A condition in which the chest is not able to support normal breathing and lung growth. TIS is commonly associated with chest and/or spine deformities.

Thoracic Cavity: The chest cavity, enclosed by the ribs, which contains the heart and lungs.

Thorax: The area of the chest composed of the spine, ribs, and breastbone.

Ultrasound Imaging: Imaging technology that uses sound waves to image bones, organs, and soft tissue.

Vertebrae: One of the 33 bones that make up the spine.

X-ray Imaging: Imaging technology used to image bones or the skeleton.

NOTES

NOTES


PATIENT AND FAMILY GUIDE

MAGEC[®]

NONINVASIVE GROWTH MODULATION



For more information about this product,
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