PATIENT AND FAMILY GUIDE

MAGEC®

Create more MAGEC moments

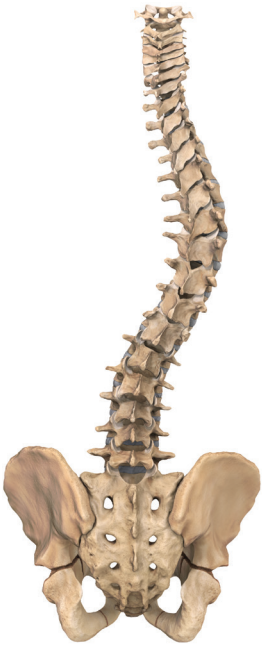
Table of Contents

Introduction

What is scoliosis?

Anatomy:

Viewed from the front or back, the spinal column should be straight. When scoliosis is present, you will typically 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°



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. 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.

Options available for treatment

The traditional surgical treatment for patients with moderate to severe cases of EOS requires an initial surgery (typically between ages 5-7), where spinal implants are implanted to gain control of the deformity.

Surgical treatment options:

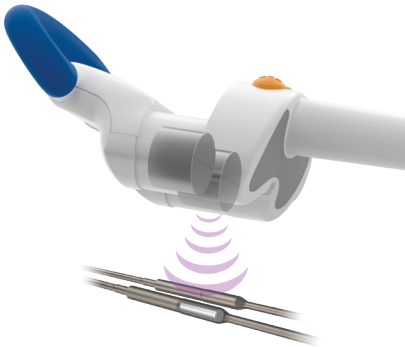
Traditional "distraction-based" treatments are considered "growth-friendly," and utilize "growing rods" that can be distracted (lengthened) as the child grows. Following implantation of growing rods, patients will generally undergo a planned distraction surgery approximately every six months, allowing for continued growth during treatment. This can add up to an additional 14 procedures beyond the initial surgery.

Another surgical treatment known as **"guided growth"** utilizes spinal implants to control the deformity while allowing the spine to translate along the rods as the child grows.

Finally, **"compression-based"** treatments exist where the spinal implants halt growth on the curvy, "overgrown" side of the spine to allow the other side to catch up.

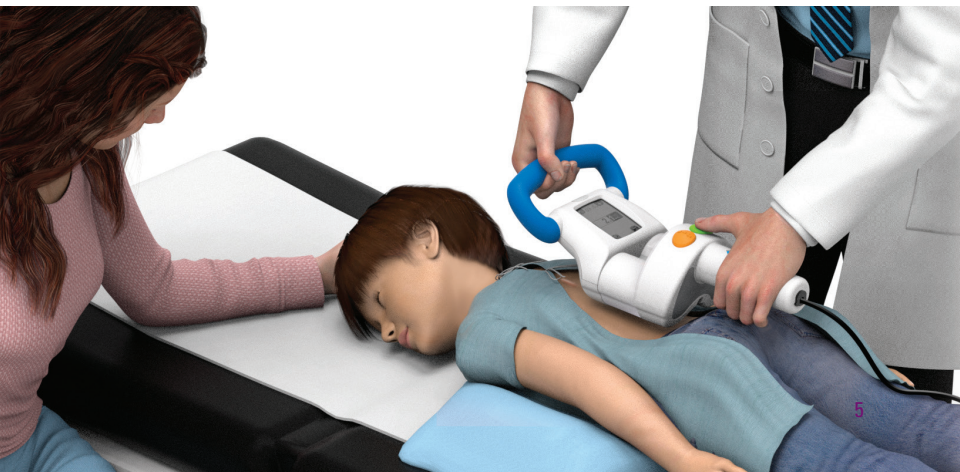
The MAGEC® system: a novel approach to EOS treatment

NuVasive®, along with thought leaders in pediatric spinal deformity, recognized the need for an alternative form of EOS treatment—the MAGEC system. **MAGEC is a distraction-based system that is designed to reduce and potentially eliminate the series of invasive surgeries required to accommodate patient growth throughout traditional EOS treatment.**



Noninvasive growth modulation

The MAGEC system uses growing rods similarly implanted as with traditional approaches, but with subsequent noninvasive distractions. Planned distractions take place in an office setting, 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 typically decide when the patient has matured enough to remove the MAGEC rods.



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;

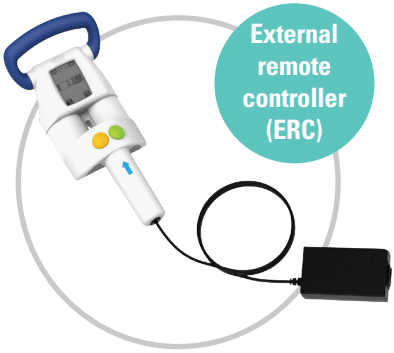
- A handheld **external remote controller (ERC)** that is used at various times after implantation to distract the implanted MAGEC rod from outside of the body.

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.

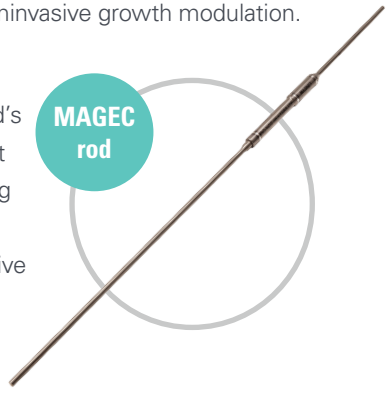
The rod distractions allow the doctor to drive or follow natural patient growth until he/she deems the MAGEC rod has achieved its intended use. At this point, the MAGEC rod will typically be explanted (removed).

The MAGEC® system includes the following technology:



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 child's spine. The rod is lengthened through a noninvasive procedure in an office setting.



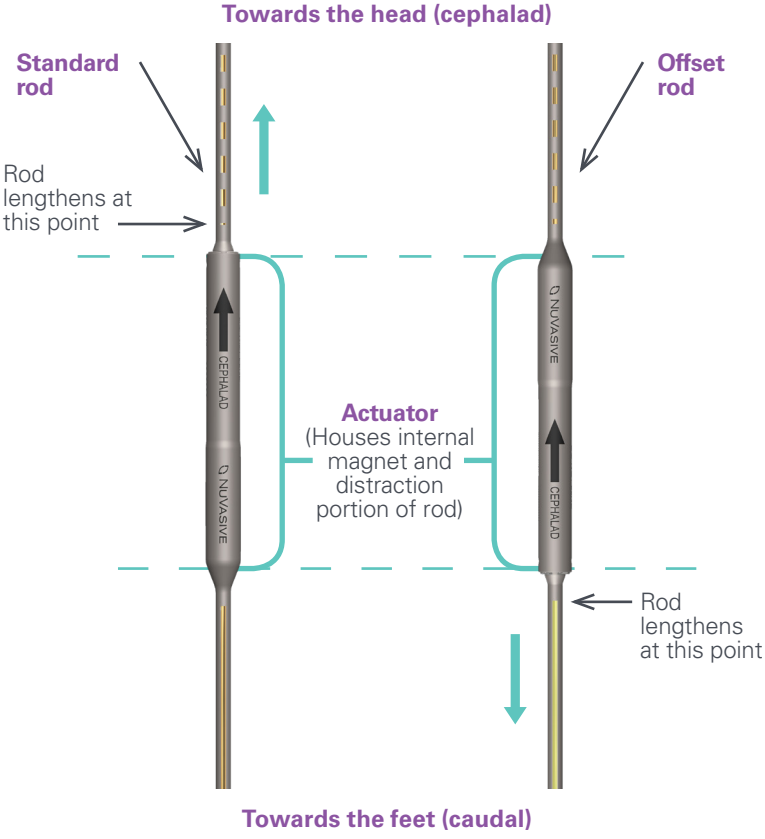
The MAGEC manual distractor is used to verify MAGEC rod functionality before implantation into the spine.

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.

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**



Before MAGEC® surgery

What you can do before surgery

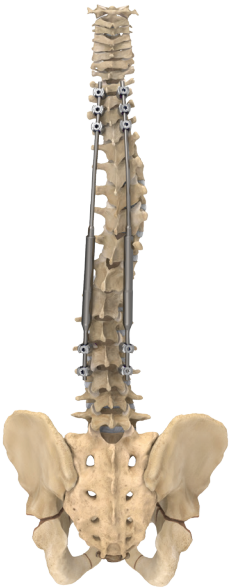
The child's doctor will typically discuss with you the different ways to treat EOS, including the MAGEC system and other alternative therapies. The doctor will generally also talk to you about the child's exact condition and needs, as well as the risks and benefits of having a spinal growth rod. Discuss the child's medical history and/or current conditions with the doctor before deciding on a treatment plan. It is the responsibility of the child's physician to address all risks, benefits, and alternative options before moving forward with the procedure.

If you decide MAGEC is the treatment choice for the child, typically the doctor will provide the information needed to get the child ready for the surgery. The doctor will also talk to you about the limitations the child may experience and cautions to be aware of once the MAGEC rod has been implanted. X-ray images will typically be taken of the child prior to surgery for baseline measurements.

During MAGEC® surgery

What happens during the surgery?

During the child's surgery, the doctor will typically 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 typically 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 typically be secured to the anchors at the foundation sites.



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

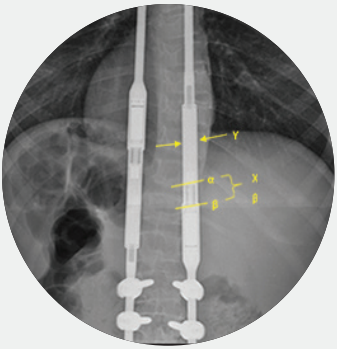
After MAGEC® surgery

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 the child's growth. The postoperative treatment plan will typically include how often the child should return to the doctor's office for these distractions. At these visits, the child will lie in a prone (lying face down) or other position exposing his or her back, and the MAGEC Wand will be used to locate the magnet within the implant. The MAGEC external remote controller (ERC) will typically 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 the child. X-ray or ultrasound images will typically 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.

How often does distraction occur?

The doctor's treatment plan will be more specific; however, patients can expect to have distractions every three months (on average) until the doctor deems the treatment complete. The distraction results may be checked with X-ray or ultrasound technology. Discuss any concerns you may have with repetitive X-ray exposure with the doctor. Based on distraction results, the child's treatment plan may be adjusted.

What happens during growth?

As the child grows, the MAGEC® rod(s) will be distracted to drive or follow the growth of their spine. When the child's physician believes the growth treatment is complete, the rod(s) may be removed. At that point, the doctor may recommend other treatment options to address any remaining deformity, such as a final fusion procedure.

What lifestyle changes may be expected?

This question is best directed to the child's surgeon and healthcare providers, as it varies for each individual. Similarly, the child's surgeon and healthcare providers can address the appropriate activity level for the child following implantation of the MAGEC rod, and throughout the distraction process. It is very important to discuss this with the child's surgeon and healthcare providers before the child engages in any physical activities.

When should the doctor be contacted?

The child's doctor will provide guidance on when to contact him or her outside of normally scheduled appointments. You should contact the child's doctor immediately if the child feels any abnormal pain or discomfort. Discuss any pain and discomfort the child is having with the doctor during the follow-up visits.

Benefits of the MAGEC® system

Some of the expected 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
- 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
- Reduced frequency of exposure to anesthesia[1]
- May limit chances of acquiring infections[2]
- Avoidance of multi-day stays in the hospital every six months
- May prevent the repetitive anxiety associated with these distractions[3]
- Lower overall cost of treatment when compared to a surgical distraction procedure used for traditional growing rods[4]

With the MAGEC system, the patient and family experience of receiving treatment for EOS is transformed.

Risks of the MAGEC® system

As with all surgical procedures, complications can and do occur with the MAGEC system. Surgery to treat pediatric scoliosis can be challenging due to the age and size of this unique patient population. Complications may include:

- Slow or poor healing of the wound and/or bone
- Anchors that move or break
- Rod breakage
- Implant prominence
- Injury to the spinal cord
- Infection
- Pulmonary issues
- Localized tissue discoloration

This is not a complete list of all possible complications. Discuss risks with the surgeon prior to the child's procedure. See the following pages for further indications, contradictions, warnings, and precautions.

Indications, contradictions, warnings, and precautions

MAGEC® indications

United States: The MAGEC system is indicated for skeletally immature patients less than 10 years of age with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) associated with or at risk of thoracic insufficiency syndrome. TIS is defined as the inability of the thorax to support normal respiration or lung growth.

International: The implanted rod is used to brace the spine during growth to minimize the progression of scoliosis. The rod includes a small internal magnet which allows the rod to be lengthened by use of the External Remote Controller. The rod is implanted and secured using standard fixation devices (pedicle screws, hooks and/or connectors).

The MAGEC System is comprised of a sterile single use spinal rod that can be surgically implanted using appropriate NuVasive® Reline®, Reline 4.5-5.0 (Reline Small Stature), or Armada fixation components (i.e. pedicle screws, hooks, and/or connectors).

MAGEC contraindications

- Patients with infections 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).
- Patient with a pacemaker or other active, electronic devices (e.g., ICD).
- Patients younger than two years old.
- Patients weighing less than 25 lb (11.4 kg).
- Patients and/or families unwilling or incapable of following postoperative care instructions.
- Patients with stainless steel wires or other implants containing incompatible materials.

What are the warnings for MAGEC?

The following warnings are associated with the implant component of the MAGEC system:

- The MAGEC system (including non-invasive distraction procedures using the External Remote Controller) should only be used by surgeons who are experienced with pediatric posterior spine surgery procedures and have undergone hands-on training in the use of this device. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the MAGEC should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurological complications.
- Correct selection of the appropriate implant size and correct placement of the device are essential to ensure optimal performance and function of the device. Please refer to the MAGEC Surgical Technique Guide for step-by-step instructions on the required surgical technique, including determining the correct implant size.
- The MAGEC system Implants are supplied sterile and are for single use only and cannot be reused or resterilized.
- Do not use if the sterile pouch has been damaged or is opened.
- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Do not use this device without proper training in both device implantation and adjustment.
- Ensure that the distraction length is assessed by X-ray or ultrasound imaging immediately after the non-invasive adjustment procedure, and also at a minimum of once every six months.
- The following warnings are associated with the External Remote Controller component of the MAGEC system:
- Always confirm the predicted implant adjustment length displayed by the External Remote Controller with X-ray or ultrasound measurements.
- This equipment is intended for use by healthcare professionals only.
- The External Remote Controller uses strong permanent magnets. Misuse of this system can cause serious personal injury. Make sure the work area is free of metal objects before use. This includes tools and metallic items in the work area and personal items such as jewelry, watches, keys, and cellular phones, which may be drawn to the ERC if brought too close. Always maintain a firm grip on the ERC and be very aware of other objects in your work area. Always return the system to its protective case when not in use.
- Never place the External Remote Controller near electronic media or appliances. The strong magnetic field may damage magnetic media such as floppy disks, credit cards, magnetic I.D. cards, cassette tapes, video tapes or other such devices. It can also damage televisions, VCRs, computer monitors and other CRT displays.
- Use of the MAGEC rod may result in localized tissue discoloration.

What are the precautions for MAGEC®?

The following precautions are associated with the implant component of the MAGEC system:

- During the implantation period, if a brace is used on the patient, the brace should not have any magnetic metallic components (steel, etc.) which may affect the implanted magnet.
- During the implantation period, the patient should limit their backpack weight to 20 lb (9 kg) or less.
- Assure that a sufficient curve is placed on the bendable portion of the rod to conform to the desired sagittal curve.
- Patients should be limited to those having a BMI (body mass index) of 25 or less.
- The MAGEC rod should always be used in compression, not in tension.
- Examine the implant carefully prior to use and use the MAGEC Manual Distractor to assure the implant is in proper working condition. If you suspect a component to be faulty or damaged, do not use it.
- Always implant the rod in the patient so that the words "CEPHALAD" and arrow on the actuator points toward the head (cephalad) of the patient.
- When using dual rods in a patient, the actuators should be placed at the same height as each other in relation to caudal and cephalad (see Figure 1, and Figure 2, Page 4).
- Device should be removed after the active distraction period has ended.
- Device should be removed after an implantation time of no more than two years.
- Device should be removed if skeletal maturity has been reached (e.g., open tri-radiate cartilage; skeletal maturity as defined by Risser sign).
- Device should be removed or replaced if maximum distraction length of the device has been attained and patient is not skeletally mature (e.g., open tri-radiate cartilage; skeletal maturity as defined by Risser sign).
- Utilize extreme caution when handling instruments made from magnetic materials such as stainless steel in proximity of the magnet of the actuator, as similar materials will be attracted to each other.
- When cutting the rod to the desired length, take care not to leave any sharp burrs at the site where the rod is cut.
- Do not bend the actuator.
- Do not repeatedly bend or excessively bend the rod. The rods should not be reverse bent in the same location.
- If retraction of the device is needed, never retract device more than the amount lengthened during the preceding lengthening session. Failure to follow this caution may result in pulling biological material that may have adhered to rod into internal space of actuator.
- Follow External Remote Controller (ERC) Operator's Manual and Surgical Technique Guide to assure proper alignment between the ERC and magnet of the actuator.
- This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the External Remote Controller or shielding the location.
- Only use the External Remote Controller in a manner consistent with this Operator's Manual. Any alternative use may result in injury or damage to property.
- If this equipment is damaged, beware that magnet shards from broken magnets are very sharp. Always handle broken magnets with thick protective gloves.
- There are no user serviceable components inside this device. Do not open the unit. Personal injury or damage to the equipment may result. Service should only be performed by qualified personnel.
- Only use the supplied power cord or an equivalent hospital grade cord rated for 10 amp minimum. Replacement power cords are available from NuVasive Specialized Orthopedics™
- The External Remote Controller should only be placed immediately over the area of the patient's body at the magnetic portion of the MAGEC Implant. Do not place the External Remote Controller near any other parts of the body, for example, portions of the body which may contain ferromagnetic material containing implants. When the External Remote Controller is not being actively used on the patient, it should always be kept within its protective case.

MRI safety information

Non-clinical testing demonstrated that the MAGEC system is MR Conditional. The following conditions must be followed:

- A patient with this device can be scanned in an MR system meeting the following conditions:
  - Static magnetic field of 1.5 tesla (1.5 T).
  - Maximum spatial field gradient of 3000 gauss/cm (30 T/m).
  - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 0.5 W/kg at 1.5 T.

Under the scan conditions defined above, the MAGEC system is expected to produce a maximum temperature rise of no greater than 3.7° C after 15 minutes of continuous scanning.

- **Caution:** The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MRI safety information (cont.)

Non-clinical testing demonstrated that the MAGEC® system is MR Conditional. The following conditions must be followed:

- The patient should not be permitted to roll on the table, as this motion may cause unintended lengthening/shortening of the implant.
- The External Remote Controller, Manual Distractor and Wand Magnet Locator are MR Unsafe. Do not bring them into the MRI scan room.
- In non-clinical testing, the image artifact caused by the MAGEC system extends beyond the imaging field of view when imaged with a gradient-echo pulse sequence in a 1.5 T MRI system. However, imaging in locations approximately 20 cm away from the actuator of the MAGEC system may produce images in which anatomical features may be discerned.

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.

References

[1]Yoon 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.

[2]Bess 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.

[3]Cheung 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.

[4]Su 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.

Notes

Notes

Resources

For more information about the MAGEC® system please visit:
www.nuvasive.com

If you have any questions about early-onset scoliosis or spine surgery, please call or see the child's physician, who is the only one qualified to diagnose and treat the child's spinal condition. This patient information brochure is not a replacement for professional medical advice.

MAGEC®

Noninvasive growth modulation

NUVASIVE

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