MAGEC System Patient Information Leaflet

Device Name: Spinal Distraction Rod

Model: MAGEC Spinal Bracing and Distraction System

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.

What causes scoliosis?
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.

What are treatment options?

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

Traditional Surgical Treatment
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.

Non-invasive Growth Modulation

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

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.

Lifestyle Changes
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 to Contact Your 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.

Indications
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.

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 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.
- Patients who are pregnant

Potential Adverse Events and Complications

The following list of failures and adverse events are possible with the MAGEC System. Additionally, possible residual risks are also included.

- Loss of distraction or uncontrolled lengthening which may lead to pain, loss of correction, extension of treatment, progression of deformity, and/or necessitate revision surgery.
- Rod, screw, and/or hook/anchor failures which may lead to pain, progression of deformity, or loss of correction and necessitate revision surgery
    - Local tissue discoloration (i.e., metallosis), osteolysis, local acute inflammatory response, or other harms associated with exposure to wear debris, metal nanoparticles, and elevated

titanium serum ion levels (including neurological issues and the risks associated with reproductive and developmental toxicity).
- Rod fractures in the actuator region and/or O-Ring failure may expose a patient to additional wear debris and the associated risks.
- Exposure to biohazards or non-biocompatible materials potentially leading to immunological response, skin irritation/rash/sensitization, and/or infection and which may require medical intervention.
- Failure to lengthen which may lead to delays in surgery (leading to additional blood loss and extended exposure to anesthesia), extension of treatment, suboptimal correction, and/or necessitate revision or reoperation.
- Treatment complications including implant interference and/or anatomical compatibility issues (such as implant prominence), and inappropriate sagittal balance which may lead to delays in surgery (leading to additional blood loss and extended exposure to anesthesia), inability to complete the procedure and/or cancellation of the procedure, or may result in pain, suboptimal correction, and/or necessitate revision surgery.
- Failure to follow the MRI Safety Conditions may result in diagnostic delays, stalls or malfunctions of active implantable devices, malfunction of the MAGEC rod, or tissue damage.

These lists above do not include all possible contraindications, complications, warnings or precautions. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.

Device Lifetime Information

The expected device lifetime is 2 years. The device should be removed after implantation time of no more than two years.

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.
- 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.

Incident Reporting
Any serious incident that occurs in relation to the device should be reported to the manufacturer and the Therapeutic Goods Administration (www.tga.gov.au).

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