

# Are Magec Growing Rods The Answer To Early-Onset Scoliosis?

## Early-onset scoliosis (EOS)

is only diagnosed in children under the age of 10<sup>1</sup>, who have not yet reached skeletal maturity. At this point in development, severe deformities of the spine can impair the growth of a child's lungs and heart, leading to potentially life-threatening complications.



## Traditional Treatment For Severe Scoliosis In Children

To correct a severe spinal curvature, doctors normally turn first to plaster casts or braces, but in some children, these gentler treatment methods will prove ineffective.

- One or two metal rods are implanted to brace the spine.
- As a child grows, they will undergo a series of invasive surgical procedures, in which the rods are manually lengthened (or replaced with longer ones) to correct the curvature.
- The average patient undergoes another lengthening procedure every 6 to 8 months.<sup>4</sup>
- Some children will undergo 20 invasive surgeries over the course of treatment.

Traditional growing rods are an effective treatment, but for obvious reasons, the method isn't ideal.

## Evaluating The Cobb Angle

The Cobb angle, defined first by Dr. John Cobb in 1948, is a measure of the spine's curvature. It's the standard measurement used to identify and rate progress in cases of scoliosis.<sup>2</sup>

Cobb angles of at least 10° are defined as the minimum for a diagnosis of scoliosis. In young children who are found to have Cobb angles greater than 35°, the condition is likely to progress, according to the medical consensus of the Scoliosis Research Society's Growing Spine Committee.<sup>3</sup>

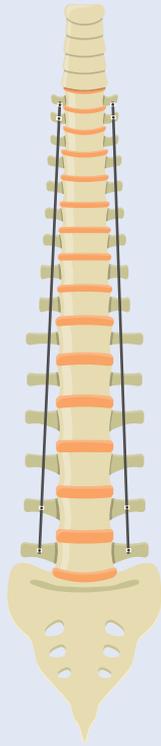
### Curvatures

<b>2% - 3%</b>	<b>&gt; 10°</b>
<b>0.3% - 0.5%</b>	<b>&gt; 20°</b>
<b>less than 0.1%</b>	<b>&gt; 40°</b>



Doctors often register decreases in the Cobb angle as a significant sign of success during scoliosis treatment.

# The Magec System: A Solution For EOS?



Now manufactured and marketed by:



San Diego,  
California

**NuVasive**  
**\$962.1 million**  
(2016 global revenue)<sup>5</sup>

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**European clearance**  
November 17, 2009<sup>6</sup>

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**FDA clearance**  
February 27, 2014<sup>7</sup>

## Enter The Magec System.

Developed and initially sold by  
Ellipse Technologies.

## Magec Growing Rods Use Magnets To Correct Spinal Curvature

ACTUATOR - HOUSES MAGNET



To lengthen a rod, doctors need only use NuVasive's Electronic Remote Controller to activate the magnet housed in a growing rod's actuator. Using this magnet technology, the growing rod extends to account for a child's growth.

It all happens from the outside, in a short outpatient visit to the doctor. In theory, no surgery is required beyond the initial procedure to implant Magec growing rods. And each extension session is painless, experts at the Children's Hospital of Philadelphia<sup>8</sup> say.



The average patient will undergo Magec lengthening every 3 to 6 months. The process continues until the child has reached skeletal maturity, which takes longer in boys than girls<sup>9</sup>. Then, the Magec growing rods are removed and the patient undergoes a final fusion surgery to prevent the spine from bending<sup>10</sup>.

## How Much Do Magec Growing Rods Cost?

Compared to traditional technologies, the Magec System's initial cost is far more expensive than traditional growing rod surgery:

**\$13,125 - \$21,875**

cost of 1 Magec growing rod

**\$64,579**

estimated cost of Magec implantation

**\$563 - \$1,125**

cost of 1 traditional growing rod

**\$34,555**

cost of traditional growing rod implantation

But in the long-run, Magec probably turns out to be cheaper, according to orthopedic surgeons at the University of Minnesota<sup>11</sup>:

**\$176**

average cost of Magec lengthening session

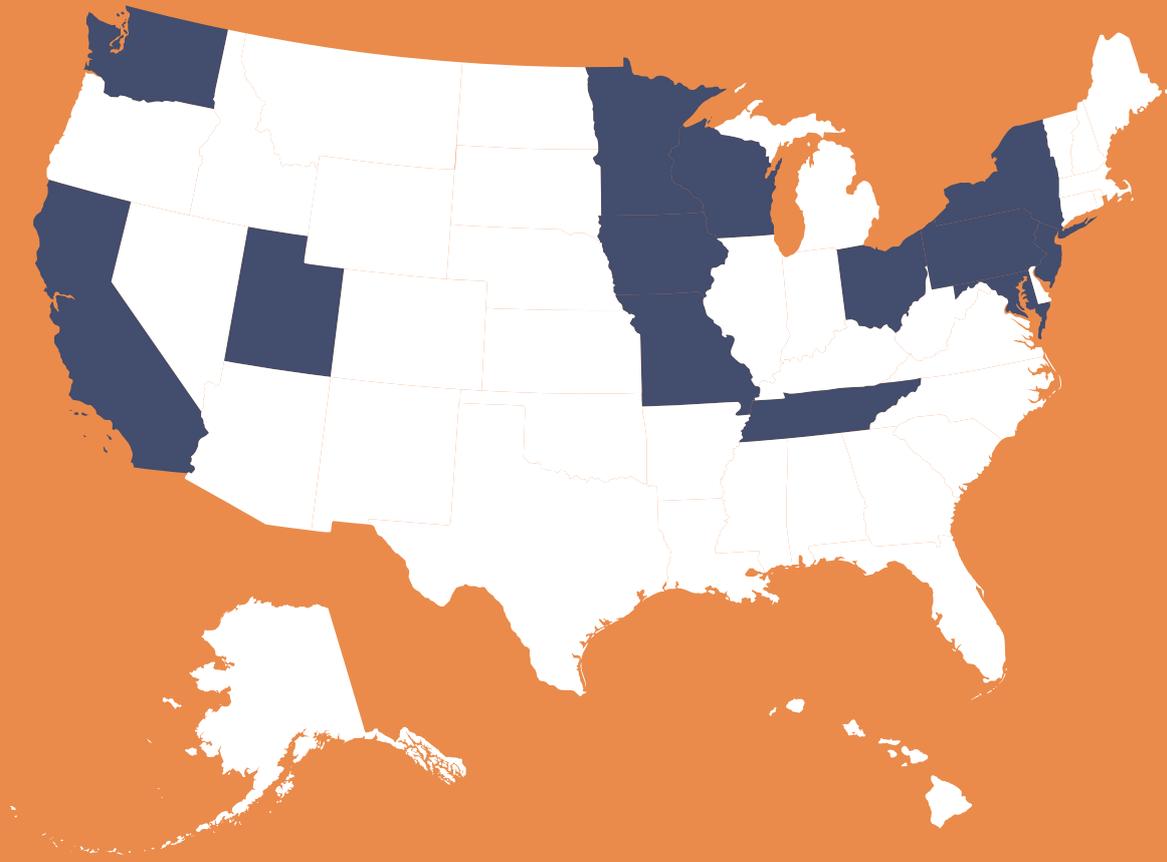
**\$6,327**

average cost of traditional lengthening procedure

Over the course of a 6-year treatment period, researchers believe that Magec will prove a more cost-effective method than traditional growing periods.

# Where is Magec Available?

As a recent innovation, Magec growing rods are only available at select medical facilities in the United States <sup>12</sup>:



## PENNSYLVANIA

- Children's Hospital of Philadelphia
- Penn State Milton S. Hershey Medical Center (Hershey)

## TENNESSEE

- Monroe Carell Jr. Children's Hospital at Vanderbilt (Nashville)

## WASHINGTON

- Children's National Medical Center (Washington, D.C.)

## MARYLAND

- Johns Hopkins Children's Center (Baltimore)

## NEW YORK

- New York Presbyterian Morgan Stanley Children's Hospital
- Stony Brook Medicine (Stony Brook)
- Cohen Children's Northwell Health (Long Island)
- University of Rochester Golisano Children's Hospital (Rochester)

## NEW JERSEY

- St. Joseph's Regional Medical Center (Paterson)

## MISSOURI

- Shriner's Hospitals For Children

- Cleveland Clinic
- The Children's Mercy Hospital (Kansas City)

## IOWA

- University of Iowa Stead Family Children's Hospital (Iowa City)

## WISCONSIN

- University of Wisconsin Hospital (Madison)

## UTAH

- Cincinnati Children's Hospital Medical Center
- Seattle Children's Hospital
- Primary Children's Hospital (Salt Lake City)

## CALIFORNIA

- Valley Children's Healthcare (Madera)

## OHIO

- Nationwide Children's Hospital (Columbus)

## MINNESOTA

- Gillette Children's Specialty Healthcare (St. Paul, Minnesota)

# Is Magec An Effective Treatment?

Compared to traditional growing rods, the Magec System is usually chosen to treat children with more severe spinal deformities. In a review of 23 studies on Magec growing rods, researchers at Britain's National Institute for Health and Care Excellence found that children who received Magec rods had an average Cobb angle of 72.4° before implantation. Traditional growing rod patients, on the other hand, were diagnosed with an average initial Cobb angle of 65.7°. <sup>13</sup>



So how does the Magec System stack up against traditional methods? Early results on the Magec System's efficacy appeared to be promising, according to a recent report in the World Journal of Orthopedics.<sup>14</sup> Britain's National Institute for Health and Care Excellence had recommended the new treatment method for children 2 years and over in a 2014 guidance, citing cost-savings and a reduction of invasive lengthening surgeries. <sup>15</sup>

## New Studies Raise Safety Concerns

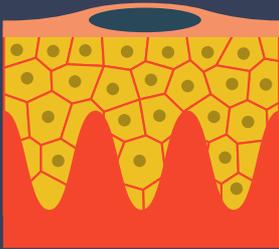
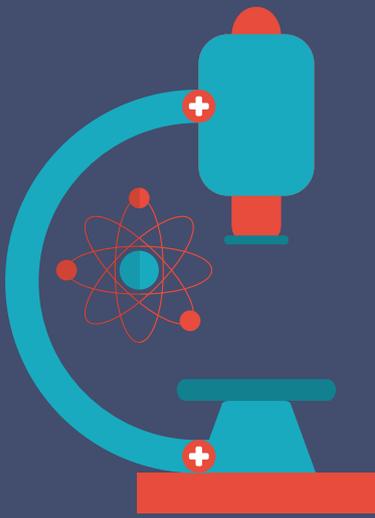
But a number of more recent medical studies have also raised concerns about the revolutionary technology's safety. As we'll see, teams of researchers around the globe have noted "substantial complication rates" in Magec growing rod patients.



The bulk of this emerging medical literature focuses on two potential problems, which may be interrelated:

## Metallosis & Premature Implant Failure

Like traditional growing rods, Magec implants are made primarily from a titanium alloy. Researchers believe that, after being implanted inside a patient, the metal components of an implant may be able to wear against one another, ultimately releasing metal debris.<sup>16</sup> If these metal particles build up in the body's soft tissues, a medical condition known as metallosis can be the result.



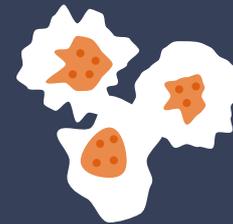
**Necrosis** (tissue death)



**Skin rash**



**Pain and inflammation  
around implant site**



**Pseudotumors**

masses of inflamed cells that resemble a tumor

Over time, the tissue death caused by the accumulation of metal particles may lead to implant loosening or fracture. In many cases, the only option to correct these problems is an invasive revision procedure, in which the compromised implant is removed and replaced with a new one.<sup>17</sup>

Metallosis has been suggested as a possible cause of premature implant failure. While researchers have been tentative to draw a conclusive link to reports of metallosis in Magec patients, a number of medical studies have observed a “substantial” rate of premature failure in Magec growing rods.



# 2016

## APRIL

Concerned by scattered reports of premature Magec failures, the British Scoliosis Society asked its member health care facilities to submit data on their own experiences with the System. 11 medical centers answered, presenting data from 195 children who had received Magec growing rods. 43 of these patients, or 22%, had undergone “unplanned revision surgeries” since their initial implantation. In 23% of these revision procedures, evidence of metallosis was noted. 8% of devices have experienced a drive pin fracture.

### **The Bone & Joint Journal<sup>18</sup>**

English physicians describe 2 cases in which the actuator pin in a Magec rod fractured. Both implants became inoperative and were removed from child patients. During revision procedures, “metallosis was identified in the soft tissues” of both children.

Actuator pin fracture in magnetically controlled growing rods: two cases.

### **The Spine Journal<sup>19</sup>**

Welsh physicians followed 8 children who received Magec rods for an average of 4 years. 6 out of these 8 patients were forced to undergo a total of 8 revision procedures. In 2 children, a rod fractured, while a 3rd revision surgery was attributed to drive pin fracture. A 4th implant failed to lengthen as intended.

Magnetic controlled growing rods for early-onset scoliosis: a 4-year follow-up.

### **The Spine Journal<sup>20</sup>**

Led by Dr. Pooria Hosseini, a Research Fellow at the San Diego Spine Foundation, surgeons followed 23 patients who were implanted with Magec rods for at least 2 years. 11 children suffered “implant-related” complications, including 2 device fractures. 10 of these patients underwent revision surgeries within the study period. 6 of the surgeries were attributed to metallosis and “failure of lengthening” (i.e. the implant did not work as intended after implantation).

Magnetically controlled growing rods for early-onset scoliosis: a multicenter study of 23 cases with minimum 2 years follow-up.

### **Spine<sup>21</sup>**

## SEPTEMBER

DECEMBER

2017

APRIL

JUNE

Surgeons from Wales cover 5 revision procedures in which a total of 7 Magec System growing rods were removed. 2 of these revision surgeries were attributed to implant fracture. After removal, 6 out of 7 rods “had tissue metallosis and pseudo-capsule surrounding the [implant] actuator.” When the rods were opened, “a significant amount of metal debris was found.”

Metallosis following implantation of magnetically controlled growing rods in the treatment of scoliosis.

### **The Bone & Joint Journal<sup>22</sup>**

Mechanical engineers in England cut open 34 Magec growing rods after removal procedures. “Titanium wear debris” was found in all 34 of the implants. More than 90% of the rods also showed evidence of wear from the outside. In over 50% of the implants, the researchers noted “O-ring seal failure.” The O-ring, designed to separate the rod’s interior from the inside of a child’s body, had broken. The article concludes by explaining, “the combination of high volumes of titanium wear debris alongside O-ring seal damage likely accounts for the metallosis reported clinically around some Magec rods.”

Analysis of explanted magnetically controlled growing rods from 7 UK spinal centers.

### **Spine<sup>23</sup>**

A group of French doctors oversaw the treatment of 30 children implanted with Magec growing rods for an average of 18 months. Within that period, 24 complications were noted, including

Magnetically controlled growing rod in early onset scoliosis: a 30-case multicenter study.

### **European Spine Journal<sup>24</sup>**





After learning of these results, a number of families have raised their concerns with our attorneys. In collaboration with the lawyers at Banville Law, the experienced product liability attorneys at Monheit Law have begun a full investigation of the Magec System. We're trying to learn everything we can about this new device. Our investigation begins with the children and families whose lives have been affected by it. If your child received Magec growing rods, our attorneys want to hear about your family's experience.

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 **877-700-9480**

 <https://monheit.com/magec-growing-rods/>



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 **BANVILLE LAW**

## WORKS CITED

<sup>1</sup> <http://www.britscoliosis.org.uk/patient-information/early-onset-scoliosis>

<sup>2</sup> [https://www.physio-pedia.com/Cobb%27s\\_angle](https://www.physio-pedia.com/Cobb%27s_angle)

<sup>3</sup> <http://www.srs.org/about-srs/quality-and-safety/position-statements/early-onset-scoliosis-consensus-statement>

<sup>4</sup> <https://thriving.childrenshospital.org/its-magec-new-type-of-scoliosis-surgery-sparks-a-smile/>

<sup>5</sup> <http://ir.nuvasive.com/static-files/cc9783b6-75f5-4e9b-8124-6fcdb988c2e7>

<sup>6</sup> <http://www.businesswire.com/news/home/20091117005523/en/EI->

[lipse-Technologies-Receives-CE-Mark-Clearance-MAGECTM](http://www.businesswire.com/news/home/20091117005523/en/EI-lipse-Technologies-Receives-CE-Mark-Clearance-MAGECTM)

<sup>7</sup> <https://www.shrinershospitalsforchildren.org/news/TPA-MAGEC>

<sup>8</sup> <http://www.chop.edu/treatments/magec-growing-rods>

<sup>9</sup> <http://www.endocrinologiapediatrica.org/modules.php?name=articulos&idarticulo=7&idlangart=ES>

<sup>10</sup> <http://www.chop.edu/treatments/magec-growing-rods>

<sup>11</sup> <https://pdfs.semanticscholar.org/5779/1f131d0f705ddb95e6afb6ea567e8c176934.pdf>

<sup>12</sup> List is not meant to represent a complete record of all US facilities that offer the Magec System

<sup>13</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4232741/>

<sup>14</sup> <https://www.wjgnet.com/2218-5836/full/v8/i4/295.htm>

<sup>15</sup> <https://www.nice.org.uk/guidance/mtg18>

<sup>16</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4598667/>

<sup>17</sup> <https://link.springer.com/article/10.1007%2Fs11999-013-2788-y>

<sup>18</sup> <https://www.ncbi.nlm.nih.gov/pubmed/28566388>

<sup>19</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26707076>

<sup>20</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26844638>

<sup>21</sup> <https://www.ncbi.nlm.nih.gov/pubmed/26974834>

<sup>22</sup> <http://bjj.boneandjoint.org.uk/content/98-B/12/1662.long>

<sup>23</sup> <https://insights.ovid.com/pubmed?pmid=28459777>

<sup>24</sup> <https://link.springer.com/article/10.1007%2Fs00586-016-4929-y>