INSTRUCTIONS FOR USE – CANADA ONLY

MAGEC SPINAL BRACING AND DISTRACTION SYSTEM

Product Description:

The **MAGEC Spinal Bracing and Distraction System (MAGEC System)** is comprised of a sterile single-use spinal rod that is surgically implanted using appropriate Stryker Xia fixation components (i.e. Pedicle screws, hooks and/or connectors, provided non-sterile, to be sterilized by the end user). The MAGEC implants are manufactured from titanium alloy (Ti-6Al-4V) per ASTM F136. The system includes a non-sterile hand-held External Remote Controller (ERC) that is used at various times after implant to non-invasively lengthen or shorten the implanted spinal rod.

The implanted spinal 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 ERC. The rod is implanted and secured using standard fixation components.

The hand-held non-invasive ERC is electrically powered. The ERC is placed over the patient's spine and then manually activated, which causes the implanted magnet to rotate and either lengthen or shorten the rod. Periodic lengthening of the rod is performed to distract the spine and to provide adequate bracing during growth to minimize the progression of scoliosis. Once the physician determines that the implant has achieved its intended use and is no longer required, the implant is explanted.

Indications for Use:

The MAGEC Spinal Bracing and Distraction 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:

- 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).
- Patients 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.
- Patients who are pregnant

Potential Adverse Events and Complications:

The following list of failures and adverse events are possible with the MAGEC System. Failure to follow the contraindications, warnings, cautions, and precautions listed in this IFU constitute off-label use and may increase the likelihood of these events.

- 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 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.

Warnings:

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 Technique Guide for step-by-step instructions on the required surgical technique, including determining the correct implant size.
- The MAGEC Spinal Bracing and Distraction 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.
- Use of the MAGEC Rods may result in localized tissue discoloration.
- Improper implantation may lead to rod over or under distraction.
- Do not use this device without proper training in both device implantation and adjustment. Refer to the MAGEC Technique Guide for step-by-step instructions on the required surgical technique and the External Remote Controller (ERC) Operator's Manual for operation of the External Remote Controller.
- 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.
- While there may be situations where anatomy and pathology only allow for single-rod MAGEC constructs, whenever possible, dual-rod constructs should be used, as single-rod constructs have been shown to fail at higher rates than dual-rod constructs.

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.

Precautions:

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 not participate in contact sports, or other high risk activities.
- During the implantation period, the patient should limit carried weight to 20 lbs. (9 kg) or less.
- Ensure 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 ensure 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).
- 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.
- After two years implantation time, continued implantation may increase the rate of adverse events or complications.
- Device should be removed if skeletal maturity has been reached (as defined by the Risser Classification).
- Device should be removed or replaced if maximum distraction length of the device has been attained and patient is not skeletally mature (as defined by the Risser Classification).
- 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 MAGEC Technique Guide to ensure proper alignment between the ERC and magnet of the actuator.

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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.

The following precautions are associated with the External Remote Controller component of the MAGEC System:

- 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 Amps 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.

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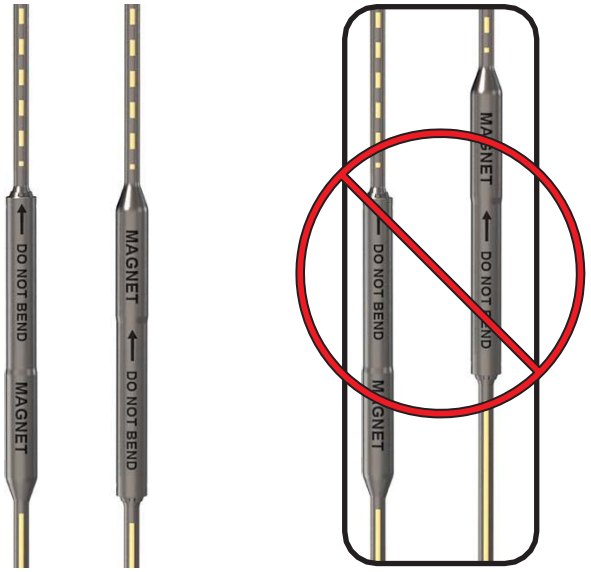
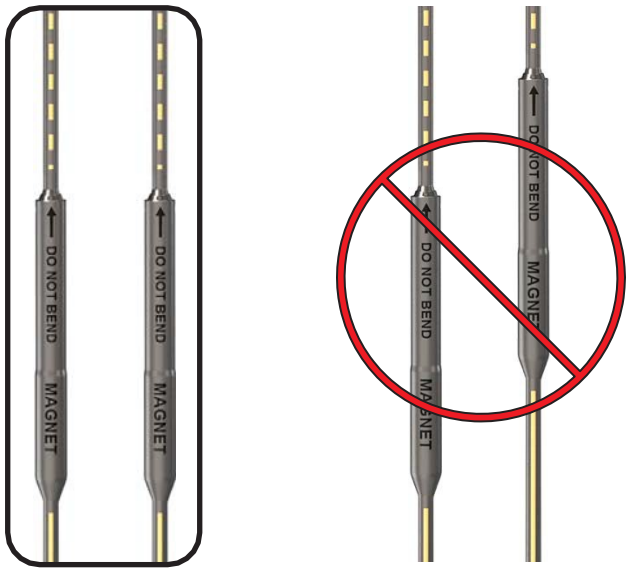
The MAGEC Rod is available in two general configurations, Standard (S) and Offset (R). The Standard and Offset rods use the same mechanism, but the magnet is located at opposite ends of the actuator. When using a Single rod construct, use the Standard (S), model rods. When using a Dual rod construct, use two Standard (S) models or a Standard (S) model and an Offset (R) model rod combination (See Figure 1 and 2 below for the configurations and correct alignment of the rods.) Two Standard rods can be used in combination in a dual rod configuration if the surgeon preference is to distract the rods at the same time. A Standard and Offset rod may be used in combination in a dual rod construct if the surgeon preference is to distract the rods individually. Please refer to the MAGEC Technique Guide.



Correct Alignment Incorrect Alignment

Figure 1: Standard/Offset Dual Rod Combination



Correct Alignment Incorrect Alignment

Figure 2: Dual Standard Rod Combination

The Standard and Offset rods are available in three diameters, 4.5 mm and 5.5 mm and 6.0 mm. The 5.5 mm rod is designed for patients 80 lb. (36 kg) and less. The 4.5 mm rod is designed for patients 60 lb. (27 kg) and less.

For optimum results, careful pre-operative diagnosis and planning, meticulous surgical technique and extended postoperative care by experienced spinal surgeons are essential. Prior to use, the surgeon should be specifically trained in the use of the MAGEC Spinal Bracing and Distraction System along with the associated instrumentation to facilitate correct selection and placement of the implants.

Pre-Implantation Test:

MAGEC MANUAL DISTRACTOR Description & Intended Use:

The MAGEC Manual Distractor is used to test the functionality of the device by manually distracting the MAGEC rod. During an implantation procedure the MAGEC rods may be trimmed or bent to the preferred contour by the physician. Note: The larger diameter actuator section of the implant should never be bent or trimmed. Improper cutting or bending of the implant may cause damage to the actuator. The MAGEC Manual Distractor can be used after cutting and bending to verify that the implant is functioning (distracting) properly.

Precautions:

- The MAGEC Manual Distractor is supplied sterile and is for single use only. The accessory instrument cannot be reused or resterilized.
- Do not use instrument if the sterile pouch has been damaged or is open.
- Before using the MAGEC Manual Distractor, remove the silicone caps on each end and discard.

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Distraction Test Procedure:

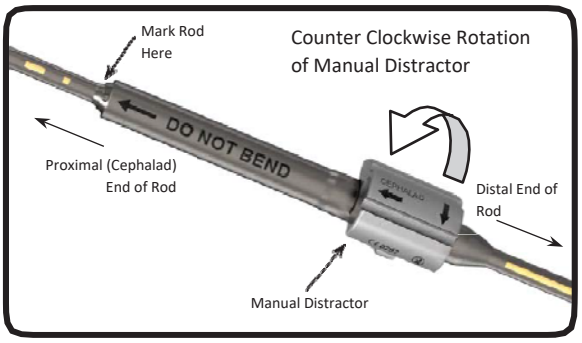
1. Ensure that the MAGEC Manual Distractor is in its original package.

2. After the MAGEC Spinal Implant has been trimmed and bent to the desired configuration, slide the MAGEC Manual Distractor over the implant zone marked with the letters "MAGNET" while maintaining standard sterile technique. Note that the MAGEC Manual Distractor will self-align over the zone marked "MAGNET."

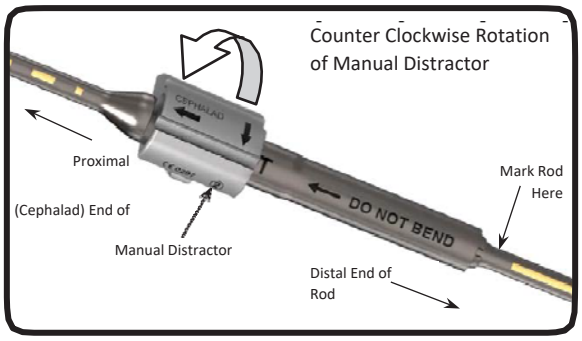
3. Rotate the MAGEC Manual Distractor, by hand, about the centerline axis of the actuator counterclockwise when viewed from the distal end of the implant with the arrow pointed up (cephalad). This will cause the implant to distract (lengthen).

4. It is recommended that four (4) full counterclockwise rotations are performed to ensure the rod is properly functioning. After confirmation, three (3) full clockwise rotations should be performed to return the rod to its neutral position. Three full rotations of the MAGEC Manual Distractor are equivalent to 1mm of distraction length. **It is recommended to mark the distraction rod with a sterile marker to aid in visualizing rod distraction and retraction.**

5. It is recommended that the rod NOT be retracted more than it was distracted (lengthened).



Standard Rod



Offset Rod

Implantation Procedure:

- Refer to the MAGEC Technique Guide for the implantation procedure.

Post-Operative Procedures:

- Refer to the MAGEC Technique Guide and the External Remote Controller (ERC) Operator's Manual prior to performing an adjustment of the MAGEC rod using the ERC.

Implant Removal:

- At the time deemed appropriate by the physician, the implant will be removed using standard surgical technique.
- Return the explanted product to NuVasive Specialized Orthopedics following instructions provided by the company. Please call **1-866-GLOBUS1 (OR) 1-866-456-2873** to obtain instructions or if you have any questions.

Other Information:

- Sterilized by Gamma Irradiation Sterilization
- Do not attempt to re-sterilize the MAGEC Spinal Bracing and Distraction System Implantable components. Steam or Ethylene Oxide gas will not reach the internal portion of the actuator, including retracted rod.
- Do not sterilize the External Remote Controller (ERC).
- Please refer to the MAGEC packaging label for the expiration date of the implantable device.

Adverse Events:

The safety and probable benefit of the MAGEC System was evaluated through a retrospective, multi-center, single arm, and open label series for children who underwent either a primary or revision spinal bracing procedure using the MAGEC System. A total of 54 subjects at 15 sites were enrolled in the MAGEC retrospective study and analyzed for Baseline characteristics and Safety.

A total of 66 adverse events occurred in 54 subjects yielding a mean of 1.2 adverse events per subject enrolled in this study. Of these 66 adverse events, 18 were serious adverse events, 28 were MAGEC device related, and 40 were implant related (MAGEC or other implant). Fourteen (14) of the 18 serious adverse events were MAGEC device-related. All serious adverse events resolved and there were no unanticipated adverse events in this study.

There were 21 adverse events observed in the 13 single rod subjects yielding a mean of 1.6 adverse events per subject. There were 45 adverse events observed in the 41 dual rod subjects yielding a mean of 1.1 adverse events per subject. A total of 54 adverse events were observed in the 30 de novo subjects (mean of 1.8 adverse events per subject) and 12 adverse events were observed in the 24 revision subjects (mean of 0.5 adverse events per subject).

A total of 34 adverse events occurred in the 4 subcutaneous implantation subjects (mean of 8.5 adverse events per subject) while a total of 32 adverse events occurred in the 50 sub muscular implantation subjects (mean of 0.6 adverse events per subject).

There were 9 adverse events that were observed at the operative procedure and 57 which occurred during the follow-up period. A total of 6 adverse events that were related to the anchor and fixation components used to fixate the MAGEC System to the spine.

Of the 95 MAGEC devices implanted in this study, 7 broken rods occurred in 6 subjects. Adverse Events were categorized and are presented in Table 1.

Table 1: Summary of Adverse Events

Implant Related Adverse Events	
Adverse Event	Frequency
Device/fixation fracture	8
Device/fixation migration	8
Pain	8
Failure to distract	5
Loss of distraction	5
Infection	3
Allergic reaction to device (metal allergy)	1
Skin erosion due to prominence of implants	1
Surgical wound complication	1
Surgery Related Adverse Events	
Adverse Event	Frequency
Fever	3
Nausea and/or vomiting	3
Abnormal sensation in extremities	1
Anemia	1
Dizziness and giddiness	1
Flatulence and related conditions	1
Low blood volume	1
Pain	1
Systemic Related Adverse Events	
Adverse Event	Frequency
Influenza	10
Abnormal enzyme levels	1
Cough	1
Rhinitis	1
Dermatitis	1

Procedure Related Complications (Implantation)

Procedure related complications at implantation are defined as adverse events related to the procedure to implant the MAGEC system. There were 12 occurrences of adverse events related to the operative procedure to implant MAGEC out of 66 total adverse events for all subjects (18.18%). Of these 12 occurrences, 1 was a Serious Adverse Event that also required surgical intervention. This event resolved with the additional surgery to remove a pedicle screw.

Procedure Related Complications (Distraction Visits)

Procedure related complications at distraction visits are defined as adverse events occurring at the time of distraction (lengthening) of the MAGEC system. There were 3 occurrences of distraction related adverse events out of 66 total adverse events for all subjects (4.55%). Two adverse events were pain related to distraction and one adverse event was subject crying during the distraction procedure. Of these 3 occurrences, none were serious and none required surgical intervention. All events were considered resolved.

Adverse Events Throughout Follow Up

Adverse events throughout follow up are defined as adverse events that occurred after implant of the MAGEC system. A total of 9 adverse events were observed at the time of implant, and 57 adverse events occurred during the follow up period out of the 66 total adverse events for all subjects (86.36%). Of these events, 28 were device related and 18 were categorized as serious. All serious adverse events were resolved, and all but one adverse event was resolved.

Unplanned Surgical Procedures

There were 21 unplanned surgical procedures during the course of MAGEC treatment on the study subjects. Of these procedures, 14 were reported as possibly related to the device, 4 were reported as not likely related to the device, and 3 were unknown. There were 13 unplanned surgical procedures that occurred in de novo subjects while 8 procedures occurred in revision subjects.

Summary of Clinical Investigations:

Objective

The safety and probable benefit of the MAGEC System was evaluated through a retrospective, multi-center, single arm, and open label series for children who underwent either a primary or revision spinal bracing procedure using the MAGEC System.

Inclusion and Exclusion Criteria

The inclusion criteria requirements were:

1. Early onset spine deformity as defined by criteria #2 and#4 below
2. Cobb angle measurement of 30 degrees or greater as measured on coronal plane radiograph at the time of primary spine surgery
3. Thoracic spine height (T1 to T12) less than 22 cm at the time of primary surgery
4. Chronological age less than 11 years old at the time of MAGEC implant
5. Implanted with the MAGEC System as either a primary or revision internal bracing procedure
6. Patient has been implanted with the device for a minimum of 6 months
7. Patient and/or caregiver signed informed consent for the use of their personal private data

Patients were excluded from the study if the patient/caregiver declined to sign the informed consent for the use of their personal private data.

Subject Population and Demographics

A total of 54 subjects at 15 sites were enrolled in the MAGEC retrospective study and analyzed for Baseline characteristics and Safety; 51 of those subjects were included in the full Probable Benefit Analysis. Subject accountability for this study is included in Figure 1.11.4-1 on the following page. To avoid selection bias in this study, no qualifying patients were excluded unless they declined to provide informed consent (except in the case where waiver from informed consent was granted by the governing Ethics Committee). The enrollment of both males and females was permitted into the MAGEC retrospective study analysis, thus reducing gender bias.

The probable benefit endpoints were summarized separately for Primary (de novo) versus Revision study subjects and stratified by device implant types (Single versus Dual Rod). A summary of the type of implantation procedure performed on the subjects is presented in the table below:

Table 2: Implantation Procedure Type

	De Novo Subjects	Revision Subjects	Total Subjects
Single Rod Implantation	9	4	13
Dual Rod Implantation	21	20	41
Total	*30*	*24*	*54*

Comparison of OUS vs US use of Growing Rods

To compare the surgical technique used for patients in the United States with those outside, NuVasive Specialized Orthopedics contacted the Growing Spine Study Group (GSSG) to obtain information regarding surgical methods used in the United States. The GSSG database was queried to determine rod construct use. Table 1.11.4.1-1 compares rod usage in the MAGEC OUS and the GSSG US cohorts. Of the 54 subjects enrolled in the OUS MAGEC retrospective study, 13 (24.1%) were implanted with a single rod construct and 41 (75.9%) were implanted with a dual rod construct. In the U.S. GSSG study cohort of 430 subjects, 89 (20.7%) were implanted with a single rod construct and 341 (79.3%) were implanted with a dual rod construct.

This data illustrates that surgical rod configuration method used in the population studied outside of the U.S. in the MAGEC cohort is applicable to that used in the U.S. population intended for the MAGEC system.

Table 3: Rod Usage; MAGEC OUS vs. GSSG US

	MAGEC (N=54)	GSSG – US (N=430)
Single Rod	13 (24.1%)	89 (20.7%)
Dual Rods	41 (75.9%)	341 (79.3%)

Non-operative management for scoliosis patients typically consists of bracing and casting to prevent progression of the spinal curve. These techniques can both be performed before growing rod surgery and afterward to provide additional support postoperatively. The GSSG database does not record non-operative management in the preoperative period. Of the 54 MAGEC subjects enrolled, 19 (35.2%) were postoperatively braced, no subjects underwent postoperative casting, 33 (61.1%) were not prescribed with either postoperative bracing or casting, and 2 (3.7%) were unknown. In the U.S. GSSG cohort of 430 subjects, 210 (48.8%) were postoperatively braced, 19 (4.4%) underwent postoperative casting, 96 (22.3%) were not prescribed with either postoperative bracing or casting, and 105 (24.4%) were unknown.

Table 4: Non-operative Management; MAGEC OUS vs. GSSG US

	MAGEC (N=54)		GSSG – US (N=430)	
	Pre-Op	Post-Op	Pre-Op	Post-Op
Bracing	21 (38.9%)	19 (35.2%)	Not recorded	210 (48.8%)
Casting	5 (9.3%)	0 (0.0%)	Not recorded	19 (4.4%)
Other	1 (1.9%)	0 (0.0%)	Not recorded	0 (0.0%)
Not prescribed	12 (22.2%)	33 (61.1%)	Not recorded	96 (22.3%)
Unknown	15 (27.8%)	2 (3.7%)	Not recorded	105 (24.4%)

The findings from the GSSG database representing US standard of care demonstrate a close parallel to the surgical technique provided in the OUS cohort followed in the MAGEC Retrospective study. In terms of surgical technique, the choice of rod configuration (e.g. dual vs single rod construct) used was similar between the two cohorts with Chi-squared test between both comparators resulting in a p-value of 0.5664. This validates the assumption that patients with early onset scoliosis who are candidates for surgical treatment are typically implanted in the same manner between both OUS and US patient populations. In comparison of non-operative management, the data illustrates that standard of care in the post-operative period was prescribed more for the U.S. GSSG cohort than the MAGEC OUS cohort. Analysis between the cohorts show that bracing was the main method used in both the MAGEC OUS (35.2%) and the GSSG US (48.8%) cohorts. Casting was not used in the MAGEC OUS cohort but was used seldomly in 4.4% of the GSSG US Cohort. In a large percentage of subjects, post-operative management was either not prescribed or was unknown (64.8% versus 46.7% in the MAGEC OUS and GSSG US cohorts, respectively).

Primary and Secondary Endpoints

In assessing probable benefit, the endpoints chosen in the study included Cobb angle correction in the coronal plane, thoracic spine height increase, improvement in space available for lung (SAL), coronal and sagittal balance, reduction in the number of subsequent surgical procedures, and weight gain. Radiographs were measured by an independent core lab. The primary and secondary endpoints that were used for the study are outlined in the table below:

Table 5: Primary and Secondary Study Endpoints

	Primary Endpoint	Secondary Endpoint
Probable Benefit	• Cobb angle correction and progression • Thoracic spine height increase • Improvement in Space available for lung (SAL)	• Coronal balance • Sagittal balance • Reduction in number of Subsequent surgical interventions following initial implantation • Weight gain
Safety	• Procedure related complications (during implantation) • Procedure related complications (during distraction visits) • Adverse events through follow up period • Unplanned surgical procedures	

Results of Probable Benefit Endpoints

The Probable benefit was measured to the following criteria as described in Table 6 below. The criteria establishes subjects who have demonstrated improvement, maintenance and worsening of the probable benefit endpoints. These criteria were evaluated at the last available radiograph as compared to baseline.

Table 6: Primary Probable Benefit Success Criteria

Endpoint	Worsening	Maintenance	Improvement
Cobb angle	Cobb progresses > 5°	Within ± 5°	Cobb decreases > 5°
Thoracic spine height	TSH decreases > 5 mm	Within ± 5 mm	TSH increases > 5 mm
Space available for lungs	Absolute difference from 100% changes > 5%	Within ± 5%	Absolute difference from 100% changes > 5%

Establishing the limits as described above ensures that only differences that are clinically significant are captured as improvement or worsening.

Primary Endpoints

Table 7 below details the mean change and percent change in Primary probable benefit endpoints for subjects enrolled in the MAGEC Retrospective study. Table 8 includes a summary of the Primary probable benefits of Cobb Angle, Thoracic Spine Height and Space Available for Lungs in terms of improvement, maintenance or worsening.

Table 7: Summary of Radiographic Primary Probable Benefit Endpoints – Mean Values and % change from baseline

Endpoint	Baseline	Post-Operative	6 Months	12 Months	18 Months	24 Months	Last Visit
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
De Novo Subjects							
Cobb Angle (deg)	64.4 ± 17.9 (n= 27)	34.9 ± 14.5 (n= 26)	38.2 ± 14.7 (n= 25)	39.5 ± 17.0 (n= 25)	39.3 ± 15.7 (n= 18)	39.1 ± 19.4 (n= 14)	42.9 ±17.1 (n= 28)
Cobb Angle % Change from Baseline	N/A	-46.3 ±17.5 (n= 25)	-39.6 ± 18.5 (n= 25)	-39.1 ± 18.8 (n= 25)	-35.1 ± 21.8 (n= 18)	-36.4 ± 26.2 (n= 14)	-33.6 ± 23.8 (n= 27)
Thoracic Spine Height (mm)	164.0 ± 32.2 (n= 28)	191.9 ± 27.7 (n= 23)	195.7 ± 29.5 (n= 24)	196.1 ± 30.8 (n= 26)	192.1 ± 34.0 (n= 18)	181.4 ± 35.7 (n= 14)	194.2 ±36.7 (n= 27)
TSH % Change from Baseline	N/A	18.6 ± 19.9 (n= 23)	18.9 ± 15.2 (n= 24)	19.7 ± 16.8 (n= 26)	19.4 ± 13.8 (n= 18)	19.1 ± 12.5 (n= 14)	20.2 ± 16.0 (n= 27)
Space Available for Lung (%)	90.5 ± 14.4 (n= 28)	100.2 ±12.2 (n= 25)	100.5 ± 8.8 (n= 25)	99.6 ± 6.9 (n= 25)	102.4 ± 8.0 (n= 18)	100.0 ± 13.3 (n= 14)	99.5 ±10.8 (n = 28)
SAL % Change from Baseline	N/A	11.2 ± 15.7 (n= 25)	13.5 ± 16.7 (n= 25)	9.9 ± 13.9 (n= 25)	13.8 ± 15.1 (n= 18)	12.7 ± 18.4 (n= 14)	11.6 ± 15.0 (n= 28)
Revision Subjects							
Cobb Angle (deg)	46.5 ± 15.9 (n= 23)	36.3 ± 17.7 (n= 18)	37.2 ± 13.7 (n= 16)	39.6 ± 9.1 (n= 17)	41.5 ± 19.8 (n= 8)	44.0 ± 13.2 (n= 8)	43.2 ±18.9 (n= 22)
Cobb Angle % Change from Baseline	N/A	-24.8 ±17.2 (n= 18)	-17.9 ± 14.9 (n= 16)	-15.1 ± 20.6 (n= 17)	-14.9 ± 17.3 (n= 8)	-10.4 ± 15.5 (n= 8)	-10.5 ± 21.8 (n= 22)
Thoracic Spine Height (mm)	168.2 ± 22.5 (n= 21)	178.9± 24.8 (n= 16)	177.5 ±29.4 (n= 15)	180.1 ±35.5 (n= 17)	171.3 ±38.9 (n= 7)	180.2 ±19.7 (n= 7)	178.6 ±33.8 (n= 21)
TSH % Change from Baseline	N/A	6.4 ± 7.2 (n= 15)	4.3 ± 7.3 (n= 13)	5.7 ± 8.5 (n= 15)	1.8 ± 14.2 (n= 7)	5.3 ± 8.8 (n= 7)	5.6 ± 10.3 (n= 19)
Space Available for Lung (%)	95.8 ±12.6 (n= 20)	95.8 ± 7.7 (n= 16)	95.5 ± 12.2 (n= 15)	93.6 ± 10.3 (n= 16)	100.6 ± 7.5 (n= 7)	93.6 ± 6.9 (n=7)	97.2 ± 9.4 (n= 20)
SAL % Change from Baseline	N/A	1.7 ± 13.4 (n= 14)	0.2 ± 7.5 (n= 12)	0.8 ± 12.2 (n= 13)	13.2 ± 22.4 (n= 6)	-2.9 ± 6.2 (n= 6)	4.3 ± 16.2 (n= 17)

Table 8: Primary Probable Benefit Success Summary – % improved, maintained, and worsened compared to baseline

	Cobb angle		Thoracic Spine Height		Space Available for Lungs	
Diagnosis	Response	% (n/N)	Response	% (n/N)	Response	% (n/N)
De Novo Subjects < 2 Year Follow Up N=13						
All Subjects N=13	Improved	92.3 (12/13)	Improved	100 (13/13)	Improved	69.2 (9/13)
	Maintained	7.7 (1/13)	Maintained	-	Maintained	30.8 (4/13)
	Worsened	-	Worsened	-	Worsened	-
De Novo Subjects 2: 2 Year Follow Up N=15						
All Subjects n= 15	Improved	78.6 (11/14)*	Improved	80 (12/15)	Improved	33.3 (5/15)
	Maintained	14.3 (2/14)*	Maintained	20 (3/15)	Maintained	60 (9/15)
	Worsened	7.1 (1/14)*	Worsened	-	Worsened	6.7 (1/15)
Revision Subjects < 2 Year Follow Up N=15						
All Subjects n=15	Improved	60 (9/15)	Improved	76.9 (10/13) §	Improved	23.1 (3/13) §
	Maintained	20 (3/15)	Maintained	15.4 (2/13) §	Maintained	53.8 (7/13) §
	Worsened	20 (3/15)	Worsened	7.7 (1/13) §	Worsened	23.1 (3/13) §
Revision Subjects 2: 2 Year Follow Up N=8						
All Subjects n=8	Improved	50 (4/8)	Improved	62.5 (5/8)	Improved	14.3 (1/7)*
	Maintained	50 (4/8)	Maintained	37.5 (3/8)	Maintained	57.1 (4/7)*
	Worsened	-	Worsened	-	Worsened	28.6 (2/7)*

* Probable Benefit Endpoint data for this category was not available for 1 subject with this diagnosis

§ Probable Benefit Endpoint data for this category was not available for 2 subjects with this diagnosis

Cobb Angle

In the de novo subjects, the baseline Cobb Angle was 64.4 ± 17.9° (n = 27) and at the last follow up was reported as 42.9 ± 17.1° (n = 28). The average percent change in Cobb Angle for de novo subjects at the last follow up was a decrease of 33.6% from baseline. The MAGEC Rod was shown to correct the Cobb angle of the spine in de novo subjects by 36.4 ± 26.2% at 24 months (n=14).

Revision subjects showed a smaller real and percentage correction of the Cobb Angle due to the fact that they have already had spinal instrumentation to correct their spinal deformity. In the revision subjects, the Cobb Angle at baseline was 46.5 ± 15.9° (n = 23) and at the final follow up was 43.2 ± 18.9° (n = 22). The average percent change in Cobb Angle for revision subjects at the last follow up was a decrease of 10.5% from baseline. The MAGEC Rod was shown to correct the Cobb Angle in revision subjects by 10.4 ± 15.5% (n = 8) at 24 months.

The results for de novo subjects with less than 2 year follow up in terms of Cobb Angle showed that 92.3% of subjects improved and 7.7% maintained their Cobb Angle throughout follow up, with no subjects worsening. For de novo subjects with a minimum of 2 year follow up an improvement in Cobb Angle was shown in 78.6% of subjects, while 14.3% maintained and 7.1% worsened. Worsening of the Cobb Angle was observed in 1 subject with a minimum of 24 months of follow up.

The results for revision subjects with less than 2 year follow up in terms of Cobb Angle showed that 60% of subjects improved, 20% maintained and 20% worsened. Worsening of the Cobb Angle was observed in 3 subjects in this follow up time category. For revision subjects with a minimum of 2 year follow up an improvement in Cobb Angle was shown in 50% of subjects and 50% maintained.

Thoracic Spine Height

In the de novo subjects, the baseline Thoracic Spine Height was 164.0 ± 32.2 mm (n = 28) and at last follow up was reported as 194.2 ± 36.7 mm (n = 27). The average percent change in Thoracic Spine Height for de novo subjects at the last follow up was an increase of 20.2% from baseline. The Thoracic Spine Height of the spine in de novo subjects increased by 19.1 ± 12.5% at 24 months (n=14).

Revision subjects showed a smaller real and percentage increase in the Thoracic Spine Height due to the fact that they have already had spinal instrumentation to correct their spinal deformity. In the revision subjects, the baseline Thoracic Spine Height was 168.2 ± 22.5 mm (n = 21) and at last follow up was reported as 178.6 ± 33.8 mm (n = 21). The average percent change in Thoracic Spine Height for revision subjects at the last follow up was an increase of 5.6% from baseline. The Thoracic Spine Height of the spine in revision subjects increased by 5.3 ± 8.8% at 24 months (n = 7).

The results for de novo subjects with less than 2 year follow up in terms of thoracic Spine Height showed that 100% of these subjects showed improvement as defined above. For de novo subjects with a minimum of 2 year follow up, an improvement in Thoracic Spine Height was seen in 80% of the subjects and maintenance in 20%. No patients showed a worsening in their Thoracic Spine Height.

76.9% of revision subjects with less than 2 year follow up showed improvement in Thoracic Spine Height, whereas 15.4% maintained, and 7.7% worsened. Worsening of the Thoracic Spine Height was observed in 1 revision subject with less than 24 months follow up. For revision subjects with a minimum of 2 year follow up, 62.5% showed an improvement and 37.5% showed a maintenance in Thoracic Spine Height.

Space Available for Lung

Space available for lung is (SAL) defined as the ratio of the height of the concave hemithorax compared with that of the convex hemithorax, expressed as a percentage.

In the de novo subjects, the baseline SAL was 90.5 ± 14.4 % (n = 28) and at last follow up was reported as 99.5 ± 10.8 % (n = 28). The average percent change in SAL for de novo subjects at the last follow up was an increase of 11.6% from baseline. The SAL in de novo subjects increased by 12.7 ± 18.4% at 24 months (n = 14).

Revision subjects showed a smaller real and percentage change in the Space Available for Lung due to the fact that they have already had spinal instrumentation to correct their spinal deformity. In the revision subjects, the baseline SAL was 95.8 ± 12.6 % (n = 20) and at last follow up was 97.2 ± 9.4 % (n = 20). The average percent change in SAL for revision subjects at the last follow up was an increase of 4.3% from baseline. The SAL in revision subjects changed by -2.9 ± 6.2% at 24 months (n = 6).

The results for de novo subjects with less than 2 year follow-up in terms of space available for lung showed 69.2% improved and 30.8% maintained. For de novo subjects with a minimum of 2 year follow up an improvement was seen in 33.3% of subjects, maintenance in 60% and worsening in 6.7%. Worsening of the Space Available for Lung was observed in 1 subject with a minimum of 24 months of follow-up.

The results for revision subjects with less than 2 year follow-up for the Space Available for Lung endpoint, showed 23.1% of revision subjects with less than 24 months of follow-up as having improvement, 53.8% maintained and 23.1% worsened. For revision subjects with a minimum of 2 year follow up an improvement in Space Available for lung was seen in 14.3% of subjects, maintenance in 57.1%, and 28.6% worsened. Worsening of the Space Available for Lung was observed in 2 revision subjects with at least 24 months of follow-up.

Secondary Endpoints

Table 9 below details the mean change in the results of Secondary probable benefit endpoints of coronal and sagittal balance.

Table 9: Summary of Radiographic Secondary Probable Benefit Endpoints

Endpoint	Baseline	Post- Operative	Last Visit
	Mean ± SD	Mean ± SD	Mean ± SD
De Novo Subjects			
Coronal Balance (mm)	19.3 ± 24.5 (n= 27)	18.2 ± 14.5 (n= 23)	18.6 ±20.2 (n= 27)
Sagittal Balance (mm)	36.7 ± 32.7 (n= 20)	25.2 ± 19.5 (n= 18)	35.6 ±18.7 (n= 22)
Revision Subjects			
Coronal Balance (mm)	55.8 ± 41.6 (n= 16)	23.3 ± 17.4 (n= 17)	18.6 ±18.8 (n= 19)
Sagittal Balance (mm)	17.8 ± 12.8 (n= 22)	23.6 ± 20.6 (n= 13)	44.9 ±35.9 (n= 20)

Coronal and Sagittal Balance

Coronal and sagittal balance were assessed as secondary endpoints for the MAGEC retrospective study and evaluated at baseline, post-operative, and the last follow-up visit. The mean coronal balance in de novo subjects at baseline was 19.3 ± 24.5 mm (n = 27). The coronal balance was 18.2 ± 14.5 mm (n = 23) immediately post-operative and 18.6 ± 20.2 mm (n = 27) at the last follow-up visit in the de novo patients. Mean coronal balance in revision subjects at baseline was 55.8 ± 41.6 mm (n = 16) and was 23.3 ± 17.4 mm (n = 17) immediately postoperative. Coronal balance was 18.6 ± 18.8 mm (n = 19) at the last follow-up visit in revision patients.

The mean sagittal balance in de novo subjects at baseline was 36.7 ± 32.7 mm (n = 20). The sagittal balance was 25.2 ± 19.5 mm (n = 19) immediately post-operative and was 35.6 ± 18.7 mm (n = 22) at the last follow up in de novo patients. The mean sagittal balance in revision subjects at baseline was 17.8 ± 12.8 mm (n = 22). The sagittal balance was 23.6 ± 20.6 mm (n = 13) immediately post-operative and 44.9 ± 35.9 mm (n = 20) at the last follow-up visit in revision patients.

Subsequent Surgical Procedures

In this retrospective analysis, there were 308 non-surgical distractions of the MAGEC rod using the ERC performed at follow-up visits. In addition to the 54 initial surgical implantation procedures, there were 21 subsequent surgical procedures during the course of the MAGEC treatment on the study subjects. Table 10 below details the subsequent surgical procedures throughout the study by type.

Table 10: Subsequent Surgical Procedures by Type

Reason for Surgical Procedure	Frequency of Occurrence
Rod Replacement	9
Fixation Revision	5
Rod Removal	2
Unknown	2
Rod Trimming	1
Wound Revision	1
Other Fixation Removal	1
Total 7	21

After the implantation procedure, patients return to the doctor's office or hospital for non-invasive distraction of the MAGEC rod. The distraction procedure utilizes the External Remote Controller (ERC) to lengthen the MAGEC implant to a desired amount. Traditional growing rods require patients to undergo surgery each time the rod is distracted.

Traditional growing rod procedures typically require these additional surgical lengthening procedures at 6 month intervals until conclusion of lengthening phase. If the 54 subjects in the MAGEC Retrospective study had been treated with traditional growing rods, it is expected that a total of 163 surgical lengthening procedures would have been performed on this subject subset to distract the implanted growing rod (See Table 11 below).

Due to the non-invasive distraction technology of the MAGEC System, the operative procedures required for the MAGEC System are reduced when compared to the expected number of surgical procedures needed with traditional growing rods. In this retrospective study, 21 additional surgical procedures were performed in the cohort of 54 patients. This represents an 87% reduction in the expected surgical procedures for the subjects in this study when implanted with MAGEC compared to traditional growing rods.

The table below provides an overall summary of the subjects included in this study and the follow-up time in months. In addition, the expected surgical procedures if these subjects had been treated with traditional growing rods is included.

Table 11: Subject Follow-up vs. Expected Surgical Distractions

Subject Follow Up					
	6 Months	12 Months	18 Months	24 Months	
De Novo subjects (n=30)					
Single Rod	0	1	3	5	
Dual Rod	1	5	3	11	
Revision subjects (n=24)					
Single Rod	0	0	1	3	
Dual Rod	0	12	3	5	
*Total number of subjects at each follow up**	1	18	10	24	
Expected surgical lengthenings for a patient at the noted follow up time point†*	1	2	3	4	
Expected Surgical Distractions with traditional Growing Rod (1 lengthening procedure every 6 months)	1 (1x1)	36 (18x2)	30 (10x3)	96 (24x4)	Total Predicted Surgeries: 163
Total Number of actual Secondary Surgical Procedures in the Retrospective MAGEC Cohort	2	4	5	10	Total Observed Surgeries: 21

* 1 Patient only had post-op data available and was not included in this table

† For example, a subject who had been implanted with a traditional growing rod for 6 months is expected to have had one surgical lengthening procedure. A subject who had been implanted with a traditional growing rod for 18 months is expected to have had three surgical lengthening procedures (1 every 6 months)

Weight

Subjects treated in this study, who had data for weight available at baseline and through their follow-up, demonstrated a weight gain. For 9 de novo subjects, the average weight increased from 22.2 kg to 28.4 kg (6.2 kg increase [28% increase]) over a mean follow up of 17.1 months. These 9 subjects were 7.6 ± 1.8 years of age at baseline (mean 91.2 months). All subjects who had weight data available at baseline and follow-up (n = 13) demonstrated increased weight from 21.6 kg to 27.0 kg (27.6%) over an average of 15.0 months follow up. These 13 subjects were an average of 7.3 ± 1.9 (mean 87.6 months) years of age at baseline.

According to the Centers for Disease Control and Prevention [1], the 25th percentile in weight for males and females at 91.5 months is 22.38 kg and 22.05 kg, respectively. The 25th percentile in weight for males and females at 87.5 months is 21.64 and 21.25, respectively. The Table below provides the mean weight for the 9 de novo and 13 total subjects (de novo and revision), where weight data was available, as compared to the CDC data. At baseline, the mean weight of de novo and all subjects closely resembled the 25th percentile per CDC. At the last follow up for these subjects, the mean weight closely resembled the 50th percentile per CDC at the respective mean age at the final follow up for these subjects. A summary of the weight results are presented in Table 12 below:

Table 12: Summary of Weight Comparison with CDC Weight-for-age Chart

		Subject data		CDC Data Table of Weight-for-age Charts				
				Age (months)	Percentile (Male)		Percentile (Female)	
		Mean age (months)	Mean weight (kg)		25th	50th	25th	50th
De novo (n=9)	Baseline	91.2	22.2	91.5	22.38	24.64	22.05	24.50
	Follow up	108.3	28.4	108.5	25.83	28.68	25.90	29.14
All (n=13)	Baseline	87.6	21.6	87.5	21.64	23.79	21.25	23.55
	Follow up	102.6	27.0	102.5	24.55	27.17	24.44	27.38

[1] http://www.cdc.gov/growthcharts/html_charts/wtage.htm

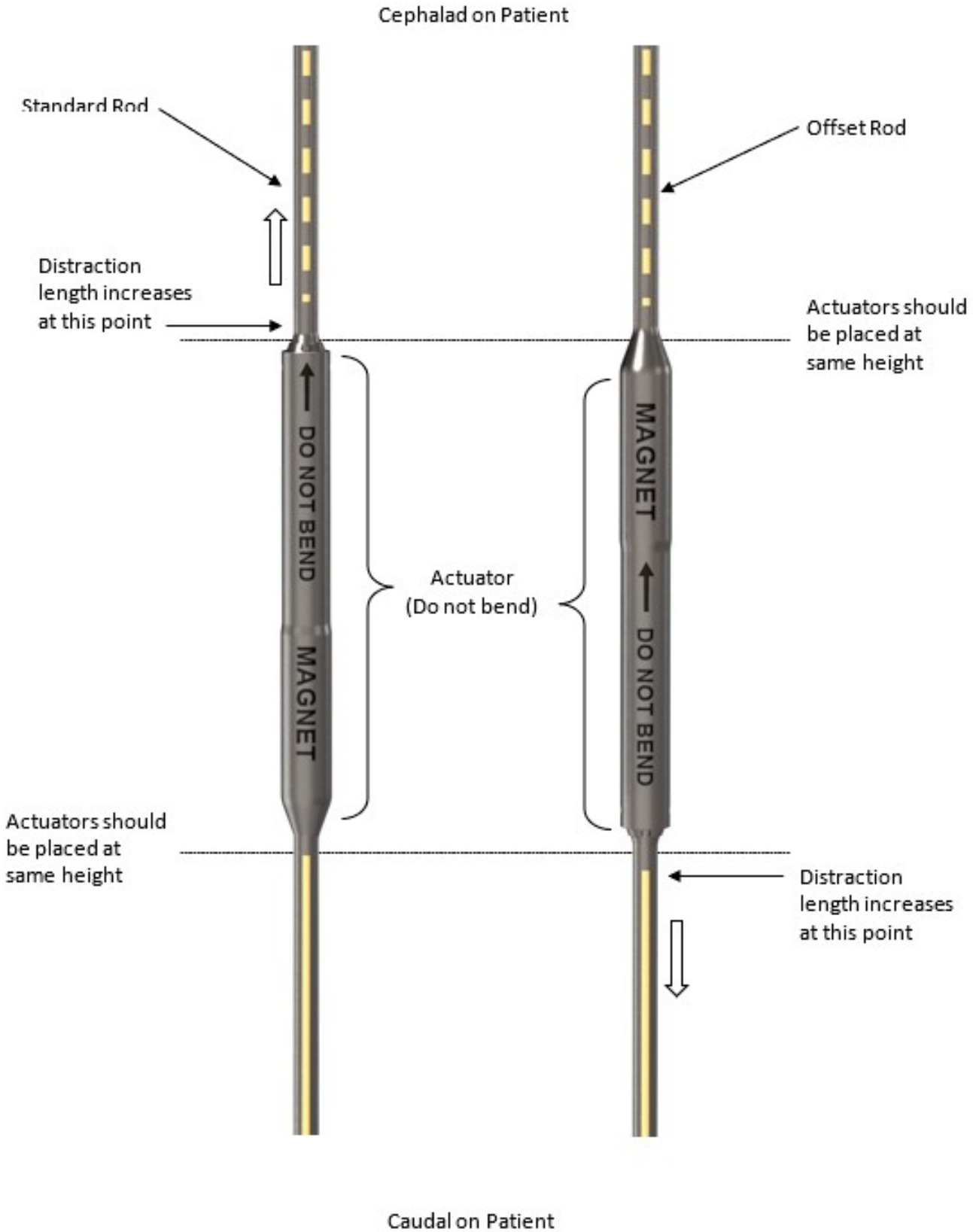


Figure 3: Dual Rod

INSTRUCTIONS FOR USE – CANADA ONLY

Symbols Definition:

Symbol	Definition
	The MAGEC System sterile components are for Single Use Only, Do not re-use
	Do not use if package is damaged or sterile barrier is broken
	Do not attempt to re-sterilize the MAGEC System Implantable components. Steam or Ethylene Oxide gas will not reach the internal portion of the actuator, including retracted rod
	Do not attempt to re-sterilize the MAGEC Manual Distractor (MMD-003)
	Do not attempt to re-sterilize the External Remote Controller (ERC)
	Non-Sterile
	Federal (US) law restricts the sale of this device for use by or on the order of a physician.
	Manufactured By
	Date of Manufacture
	Model Number
	Lot Number
 www.globusmedical.com/eIFU	Refer to Instructions for Use www.globusmedical.com/eIFU
	Expiration Date
	Sterilized using Irradiation
	Authorized European Representative
	This product has met European Union health, safety, and environmental requirements, which ensure consumer and workplace safety.

Manufacturer:

NuVasive Specialized Orthopedics
Valley Forge Business Center
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Audubon, PA 19403
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