Surgical Technique Guide
MAGEC® Remote Control
Technology for the
Treatment of Spine Deformities

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
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Introduction

Goal of treatment

The MAGEC System is designed to brace the spine and provide support for spinal deformity correction.

Indications for Use

The Ellipse MAGEC Spinal Bracing and Distraction System is intended for skeletally immature patients less than 10 years of age with 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). TIS is defined as the inability of the thorax to support normal respiration or lung growth.

The rod is employed in the following procedures, which are described in this Technique Guide:

1. Spinal Instrumentation Implantation
2. Dual Rod Implantation
3. Rod Distraction Procedure

While the technique guide covers the areas above, it is very important to review the comprehensive product Instructions for Use along with this Technique Guide.

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)

✓ Patient requiring MRI imaging during the expected period device will be implanted.

✓ Patients younger than two years old.

✓ Patients weighing less than 25lb (11.4kg)

✓ Patients and/or families unwilling or incapable of following postoperative care instructions.

✓ Patients with stainless steel wires or other implants containing incompatible materials.

NOTE: Assure that patient with implanted device does not enter an MRI unit. The effect of a high magnetic field of an MRI has not been studied with respect to the implanted magnet and is therefore unknown.
Technique Guide

Ellipse Technologies, Inc., a company focused on developing implantable technology to treat a broad spectrum of spinal and orthopedic applications, has developed the MAGEC System, a treatment for abnormal curvature of the spine. The company’s spinal products address the treatment of severe spinal deformity and focus on the children who suffer from the debilitating effects of this challenging spine disease.

MAGEC (MAGnetic Expansion Control) is an adjustable growing rod that utilizes a remote control to non-invasively lengthen the device. Following a minimally invasive procedure to implant the MAGEC Rod, the device can be distracted, or retracted, non-invasively during a set of normal outpatient visits by using the MAGEC ERC (External Remote Controller).

Concept

The MAGEC® Spinal Bracing and Distraction System is comprised of one or two sterile spinal rods that are surgically implanted using Stryker® Xia® fixation components (i.e. pedicle screws, hooks and/or connectors).

The implanted spinal rod is used to brace the spine during growth to minimize the progression of the spinal deformity. The rod includes an actuator portion with a small internal magnet, which allows the rod to be lengthened by use of the ERC (External Remote Controller).

About the ERC

The hand held non-invasive ERC is electrically powered. The device is placed over the patient’s spine where the actuator is located and then activated, which causes the magnet in the implanted rod to rotate and either distract or retract 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 spinal deformity. When the implant is no longer required, it must be explanted.

Instruments & Accessories

Special components included in the system which are discussed in this guide are as follows:

- Implant Rods which are available in 2 different sizes and 2 different lengths
- External Remote Controller (ERC)
- MAGEC Manual Distractor
- MAGEC Wand™ (Magnet Locator)
MAGEC Procedure Overview

For optimum results, careful pre-operative diagnosis and planning, meticulous surgical technique and extended postoperative care by an experienced spinal surgeon is essential. Prior to use, the surgeon should be trained in the use of the Ellipse MAGEC Spinal Bracing and Distraction System along with the associated instrumentation. In addition, follow the Instructions for Use related to Stryker® XIA® fixation components.

1. Ensure operator is trained on fluoroscopy techniques.
2. Review the MAGEC Instructions for Use. Do not use this device without proper training in both device implantation and adjustment. Refer to External Remote Controller (ERC) Operator’s Manual for operation of External Remote Controller.
3. Test the rods before implantation (see Distraction Test Procedure). If you suspect a component to be faulty or damaged, do not use it.

Cobb Angle is the angle subtended by the superior endplate of the superior vertebra and the inferior endplate of the inferior vertebra that yields the greatest angle (labeled as $\alpha$ in the figure above). Cobb Angle is measured from postero-anterior radiographic films and is reported in units of degrees.

Thoracic Spine Height Thoracic spine height is the vertical distance ($\beta$) between the superior-endplate of T1 and the inferior-endplate of T12. Thoracic spine height is measured from posteroanterior radiographic films and is reported in units of mm.
Device Selection

Device selection is primarily dependent on patient anatomy. The MAGEC rod is available in a standard and offset configuration in 4.5 mm and 5.5 mm diameters. The MAGEC System can be implanted as a single rod construct or a dual rod construct.

Diameter

Diameter of the rod is chosen based on the needs of the individual patient. These needs may involve the size, weight or age of the patient and the possible duration of time that the implant will remain in place.

Single Rod Construct

A single rod construct may be chosen based on individual patient needs or in response to existing instrumentation that has previously been implanted in the patient.

Dual Rod Construct

A dual rod construct may be chosen in order to stabilize the spine during growth or to allow for differential (separate) lengthening or shortening of one rod versus both rods.
Anchor Selection

The appropriate anchor is chosen according to a number of factors that include patient anatomy, bone quality, correction technique to be used and the forces to be applied. MAGEC has been tested pre-clinically with the Stryker® XIA® anchor system.

Anchors are the hooks, pedicle screws or cross-connectors which are used to create the foundation and secure the rod in place. Foundations are comprised of at least two pair of anchors that span over multiple vertebral levels.

Hooks

Hooks are mainly inserted in the thoracic segments of the spine according to a number of factors such as bone quality and the size of the pedicles.

Pedicle Screws

Pedicle Screws or hooks can be utilized for the proximal and distal portions of the construct. Size selection is dependent on the diameter of the rod to be implanted, and the length of the screws depend on the quality of the bone along with the size of the pedicles.

Cross Connectors

Cross connectors are used in a dual rod construct to stabilize the two implanted rods.
Implantation Procedure

Below are the step-by-step instructions to implant the MAGEC System.

**Step 1** Determine the desired anchor sites and foundation constructs for proximal and distal fixation. It is recommended that the proximal foundation utilize multiple screws or hooks. For example: claw construct or bilateral construct with cross connector.

**Step 2** Make two short incisions, one at the level of each foundation site. If two short incisions are not possible a single long incision may be used. Incisions are preferably made on either side of the expected location of the MAGEC rod and not directly over it. The proximal site on the thoracic spine may utilize pedicle screws if the size of the pedicle and the quality of the bone allows. Hooks may also be utilized. The standard fixation for the distal lumbar site will be performed with pedicle screws.

**Step 3** Expose the spine at each anchor site.

**Step 3a** [OPTIONAL] If preferred method is to fuse the anchor sites, perform fusion at this time.
Step 4 Create foundations to the spine at each anchor site.

[Option for Revision Surgery]

**Step 4a** Expose spine at any new or existing anchor site to be used.

**Step 4b** Create foundation to spine at anchor site(s).

Step 5 Cut and bend implant.

Rod bending is performed to fit the rod to the desired spinal contours. The implant must be cut, bent and positioned according to the patient’s spine. Curves in the rod must conform to the actual curves of the patient so that the proper kyphotic and lordotic angles can be actualized.

**NOTE:**
Assure that a sufficient curve is placed on the bendable portion of rod to conform to the desired sagittal curve. The longer portion of the rod (as packaged) should always be oriented cephalad (proximally) on the patient when implanted. Always place the rod in the patient so that the “CEPHALAD” arrow on the actuator points toward the patient’s head.

Step 6 Test the implant to see if it is cut and bent to fit the individual patient correctly. Tunnel the MAGEC rod subcutaneously between each anchor site. Remove rod for final contouring.

**NOTE:**
Tunneling is used to avoid unnecessary risks associated with a full open skin incision, to avoid stimulation of the periosteum, and to avoid unwanted iatrogenic fusion. Furthermore, tunneling is necessary in those cases where subfascial rod placement is utilized to avoid opening the fascia.
Step 6a Confirm that the MAGEC rod is still fully functioning in distraction and retraction modes after it has been cut and bent – these details are located on Page 11 under “Implant Distraction Test Procedure”. Move to Step 7 to fully implant and secure the rod after this test has been confirmed.

Step 7 Distract the spine as needed and secure the MAGEC rod to each anchor site.

Step 8 Secure the MAGEC rod to each anchor site.

Step 9 Close the patient per normal procedure.
Dual Rod Implant Surgery Technique

When using dual rods, a combination of two single rods or a single and offset rod combination can be used. Standard rods may be chosen if the surgeon preference is to distract the rods at the same time. A single and offset rod combination may be chosen if the surgeon preference is to distract the rods individually. When using dual rods in a patient, the rods should be chosen from the following combinations:

<table>
<thead>
<tr>
<th>5.5mm Diameter Options</th>
<th>4.5mm Diameter Options</th>
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<tr>
<td>MS1-5590R</td>
<td>MS1-4590R</td>
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<td>Two Standard Rods</td>
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<td>MS1-5590S</td>
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<td>MS1-5590S</td>
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[Important Information Regarding Dual Rod Technique]

- 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. This will assure unimpeded access by External Remote Controller (ERC). (See Figures Below)

- When using a dual rod configuration it is recommended that a cross connector be use proximally or distally, but not both proximally and distally.

- In a patient having dual rods consisting of a standard rod and an offset rod, the rods will be distracted independently (one at a time) with the External Remote Controller (ERC).

- Always test the rod following cutting and bending and prior to final implantation using the “Implant Distraction Test Procedure”.

Correct alignment of dual rods (Standard/Standard)  Correct alignment of dual rods (Standard/Offset)  Incorrect alignment of dual rods (Standard/Offset)  Incorrect alignment of dual rods (Standard/Standard)
Implant Distraction Test Procedure

To ensure the optimal success with MAGEC Implants it is very important to verify that the rods distract correctly prior to implantation. Please review and follow the important steps detailed below.

**Step 1** Sterilize MAGEC Manual Distractor prior to use as it is supplied non-sterile. Recommended sterilization instructions have been included in the Instructions for Use.

**Step 2.** Mark the rod where it first exits the actuator with a sterile marker to aid in visualizing movement of the rod.

**Step 3** Next, slide the MAGEC Manual Distractor over the implant zone marked with the letters “MAGNET” while maintaining standard sterile technique.

**NOTE:**  
*The MAGEC Manual Distractor will self-align over the zone marked “MAGNET”.*

**Step 4** 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. This will cause the implant to distract (lengthen).

**NOTE:**  
*Three full rotations of the MAGEC Manual Distractor are equivalent to 1mm of distraction length. Rotating the MAGEC Manual Distractor in the opposite (clockwise) direction the equivalent amount of turns will retract the rod back to its original packaged length. Do not retract the rod more than it was distracted at the last distraction visit.*
Post-Operative Treatment

[Patient Mobility Instructions and Distraction Procedure using the ERC.]

Provide the patient and/or caregiver with a copy of the MAGEC Patient Instructions so they know what to expect during the various phases of treatment with the MAGEC device.

It is expected that the patient will have the implanted rod in place for a few months up to two years, depending on spinal deformation severity. During this time period, while the implant is in place, it is important that they comply with the following:

- If a brace is used it must not have any metallic components which may affect the implanted magnet.
- Patient must limit backpack weight to 20% of body weight up to a maximum of 20lbs (9kg).

Once the physician determines that the implant has achieved its intended use and is no longer required, the implant may be removed using standard surgical technique. The product should be returned to Ellipse Technologies, Inc. For additional instructions about the return procedure please review the Instructions for Use.

ERC Programming

Reference the External Remote Controller (ERC) Operator’s Manual to program the patient’s prescription in the ERC.
Distraction Procedure

The distraction procedure for the implant takes approximately five minutes. To provide the appropriate post op care it is very important the physician performing the distraction reviews the External Remote Controller (ERC) Operator's Manual prior to adjusting the implanted rod. Plug the ERC into an accessible and appropriate power outlet close to the patient to ensure optimal results.

Patient Instructions:

Please have the patient remove:

- Any thick clothing like sweaters or jackets that may be covering the implant area. A thin, non-metallic shirt is acceptable.
- Any lose metal objects. (i.e. belts, buckles, jewelry, cell phones, keys, etc.)

Physician Instructions:

Step 1 Refer to the Operator’s Manual for the ERC. Select the desired adjustment mode (Target or Continuous). Enter the absolute target distraction length amount (if in “Target” mode) of the patient’s implant into the control panel on the ERC.

Step 2 Lay the patient face down on a non-magnetic examination table.

Step 3 Hold the MAGEC Wand Magnet Locator vertically by the distal end of the device. Move it to a position just above the skin surface of the patient that approximates the location of the internal magnet and allow the locator to be pulled to the strongest point of attraction. The locator will naturally align itself parallel with the internal magnet.

[Definitions]

Target Mode allows the user to input a fixed set point distance to move the implant. The ERC will automatically stop when the implant has reached the set point value.

Continuous Mode allows the ERC to run as long as the Extend or Retract Hand Piece push buttons are held. The value displayed next to the Continuous Mode increases or decreases as the implant is adjusted.

MAGEC Wand Magnet Locator

NOTES:
One will feel a strong attraction when locating the magnet with the MAGEC Wand.
[Distraction Procedure Continued]

Step 4 Make a mark with a pen or another non-permanent marker where the point of the strongest magnetic attraction occurs.

Step 5 Carefully place the External Remote Controller over patient per operating instructions.

Step 6 Position the implant locating window of the ERC over the magnet area. The ERC should be oriented along the axis of the implant with its Orientation Arrow pointing towards the patient’s head. (See Figure A and Figure B for correct orientation)

Step 7 Hold the ERC against the patient over the implant.

Step 8 Press the “Distract” or “Retract” button as needed to adjust the implant. Distract the desired amount, as viewed on External Remote Controller (ERC) display.

NOTE:
If there is any patient discomfort or pain, the External Remote Controller can be used to retract implant.

Never retract the rod more than the amount distracted at the last distraction visit.

Figure A: Appropriate Placement of ERC over Implant
Figure B: Inappropriate Placement of ERC over Implant
Distraction Measurement

The distraction length of the MAGEC rod should be assessed immediately after the distraction procedure by ultrasound or radiograph (Standard or EOS X-ray). Distraction length is measured from radiographic films and/or ultrasound and is reported in units of mm.

Ultrasound Imaging

When measuring Distraction Length on an ultrasound image, the distraction length (X) is the distance between the distal end of the actuator (α) and the proximal end of the tapered rod (β) (As shown in Figure A). Figures B and C below show an ultrasound image of a distracted portion of the MAGEC Actuator with the measurement landmarks highlighted.

**Figure A**

Ultrasound Image of the MAGEC rod. For visual perspective, the detail of the MAGEC rod has been superimposed over the ultrasound image.
Radiographic Imaging

When measuring Distraction Length on a radiographic image (Standard or EOS X-ray), there is a radiographic feature in the rod that will allows this distance to be measured. This appears as a “window” in the center portion of the actuator and is identified as the point, “X” in the figure below.

The distraction length (X) is the vertical distance between the distal end of the window (α) and the proximal end of the window (β), as shown in Figure D below.

Calibration

Calibration can be performed by measuring the diameter of the actuator portion of the MAGEC rod (Y).

The actual diameter for the rod marked “Y” is 9.02 mm. The calibration is given by the measured value (in millimeters), “Y” on the radiograph, divided by the actual value, 9.02 mm.

\[
\text{Calibration} = \frac{9.02}{\text{“Y”}}
\]

The actual distraction amount is given by the measured value (in millimeters), “X”, multiplied by the calibration.

\[
\text{Total distraction amount} = \text{“X”} \times \text{Calibration}
\]
Device Description:

The Ellipse Technologies, Inc. MAGEC® Spinal Bracing and Distraction System is comprised of a sterile single-use spinal rod that is surgically implanted using Stryker® XI® fixation components (i.e. Pedicle screws, hooks and/or connectors). The MAGEC rod is used to brace the spine during growth to minimize the progression of scoliosis. The titanium rod (Ti-6Al-4V ASTM F136) includes a small internal magnet. The MAGEC system includes a non-sterile, hand held External Remote Controller (ERC) that is used after implant to non-invasively lengthen or shorten the implanted spinal rod. The magnet in the rod is turned non-invasively by use of the ERC. The handheld ERC is placed over the location of the implant in the child’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 spinal deformities. Once the physician determines that the implant has achieved its intended use, the implant is explanted.

Indications for Use:

The Ellipse MAGEC Spinal Bracing and Distraction System is intended 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). TIS is defined as the inability of the thorax to support normal respiration or lung growth.

Contraindications:

- 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 devices (e.g. ICD)
- Patients requiring MRI imaging during the expected period the device will be implanted
- Patients younger than two years old
- Patients weighing less than 25 lbs (11.4kg)
- Patients and/or families unwilling or incapable of following postoperative care instructions
- Patients with stainless steel wires or other implants containing incompatible materials
- Patients with metal allergies and sensitivities to the implant materials (e.g. Titanium)
- Patients weighing less than 25 lbs (11.4kg)
- Patients younger than two years old

Warnings

For a complete list of warnings associated with the MAGEC System and its components, see the Instructions for Use.

- 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 Ellipse 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.
- Be sure that 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.
- Be sure that the patient with the implanted device does not enter an MRI unit. The effect of the high magnetic field in an MRI unit has not been studied with respect to the implanted magnet, and is therefore unknown.

Precautions

For a complete list of precautions associated with the MAGEC System and its components, see the Instructions for Use.

- 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.
- Be sure 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 before use and use the MAGEC Manual Distactor 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 point 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.
- 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).
- Use extreme caution when handling instruments made from magnetic materials such as stainless steel in proximity of the MAGEC Rod, as similar metals 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 MAGEC rod. The rods should not be reverse bent in the same location.
- If retraction of the device is needed, never retract the device more than the amount distracted during the preceding distraction visit. Failure to follow this caution may result in pulling biological material that may have adhered to the rod into internal space of the actuator.
- Follow the External Remote Controller (ERC) Operator’s Manual or Surgical Technique Guide to assure proper alignment between the ERC and magnet of the actuator.
**Product Reference Guide**

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<th>Model</th>
<th>Description</th>
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<td></td>
<td>MAGEC Wand (Magnet Locator)</td>
<td>MML-001</td>
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This procedure guide is not designed for formal medical training or certification. Ellipse trains only on the use of its devices and does not provide or evaluate surgical credentialing. Before performing any clinical procedure utilizing the MAGEC System, physicians are responsible for receiving sufficient training and proctoring to ensure that they have the requisite skill and experience necessary to protect the health and safety of the patient.

Failure to receive the product IFU’s and follow the notes and cautions associated with this equipment may lead to serious injury or complications for the patient.

For Reference Only. Please refer to the Instructions for Use (IFU) for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. MAGEC is not for sale in the United States. This product, and the use thereof, may be covered by one or more of the following U.S. and/or international patents: US 7,955,357, US 7,981,025, US 8,057,472, US 8,197,490. Other U.S. and international patents pending. ©2012 Ellipse Technologies, Inc. All rights reserved. ™Trademark of Ellipse Technologies, Inc.