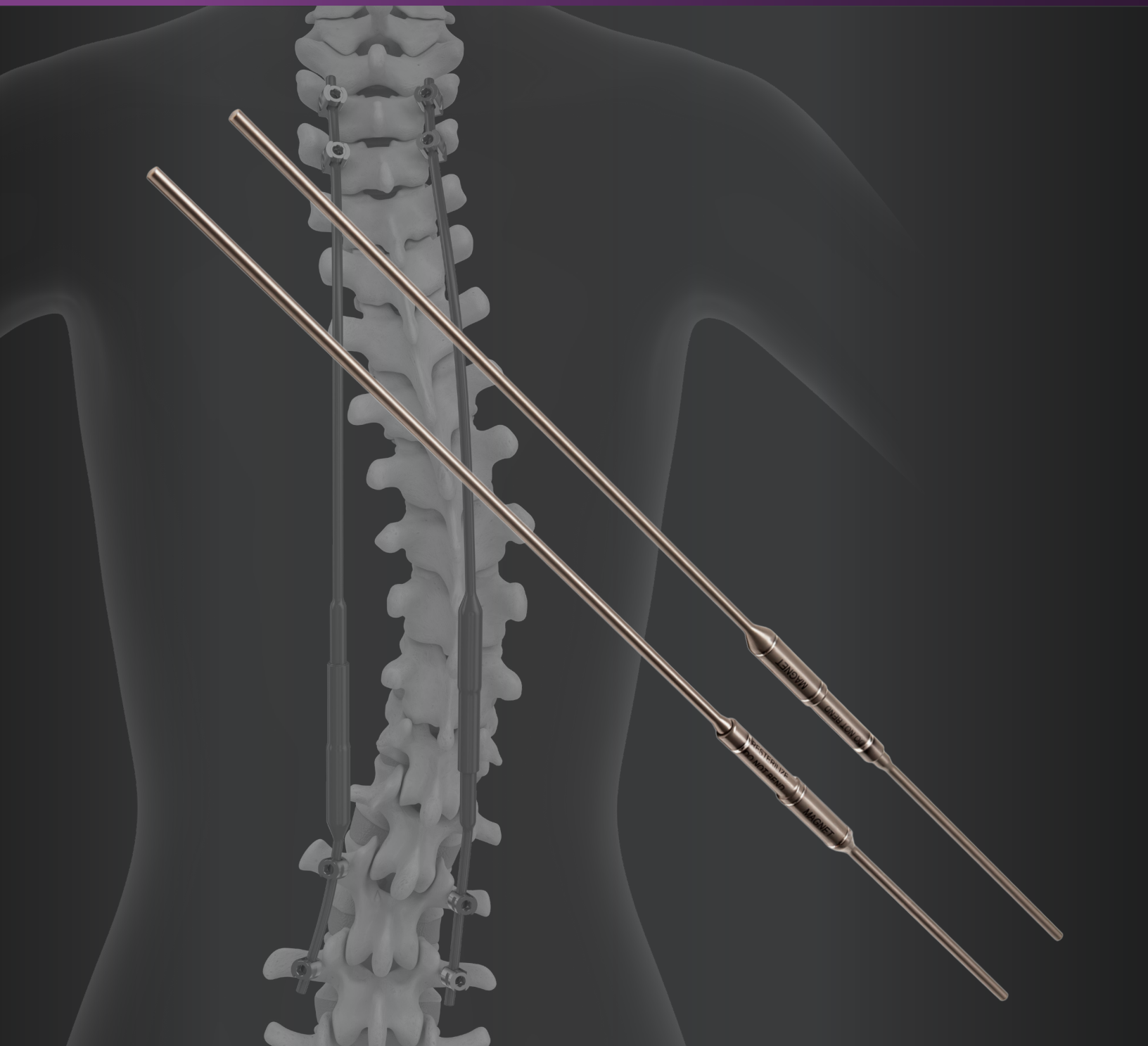
NuVasive

MAGEC

Technique Guide



This document is intended exclusively for physicians. This document contains general information on the products and/or procedures discussed herein and should not be considered as medical advice or recommendations regarding a specific patient or their medical condition.

This surgical technique guide offers guidance but is not a substitute for the comprehensive training surgeons have received. As with any such technique guide, each surgeon should use his or her own independent medical judgment to consider the particular needs of the patient and make appropriate clinical decisions as required. A successful result is not always achieved in every surgical case.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and the implant, including the use of the MAGnetic Expansion Control (MAGEC) system. It may not be appropriate for all patients and all patients may not benefit.

It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning.

This surgical technique guide provides information supplemental to information provided in the individual system instructions for use (IFU) regarding the products referenced herein.

MAGEC

CONTENTS

MAGEC SYSTEM OVERVIEW

MAGEC ROD TYPES AND ACTUATOR SIZES

Rod Diameters:
4.5, 5.5mm

Actuator Sizes:
70mm: Provides 28mm of postoperative distraction
90mm: Provides 48mm of postoperative distraction

Standard Rod:
The magnet is housed within the distal (inferior) portion of the actuator (confirm "Cephalad" arrow is pointing cephalad).
Length: 470mm

Offset Rod:
The magnet is housed within the proximal (superior) portion of the actuator (confirm "Cephalad" arrow is pointing cephalad). An Offset Rod is NOT a Standard Rod turned upside down.
Length: 470mm

ACTUATOR LENGTHS

70mm **90mm**

SURGICAL CONSTRUCTS AND ASSOCIATED DISTRACTION TECHNIQUES

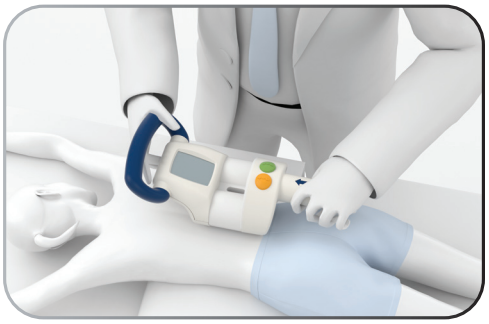
Independent Distraction:
Standard Rod + Offset Rod
Rod actuators are oriented in a way that allows the External Remote Controller (ERC) to independently control the magnet within each rod.

Coupled Distraction:
Standard Rod + Standard Rod
Two Standard Rods are used so that the ERC can simultaneously control the magnets within each rod.

GROWTH MODULATION PHILOSOPHIES FOR POSTOPERATIVE DISTRACTION

Targeted Distraction:
Surgeons plan how many millimeters of growth they desire for each rod during each individual session. They then distract the rods until the ERC reading matches their desired length of distraction.

Maximum Force Distraction:
Surgeons utilize the ERC to achieve the maximum distraction possible for each rod per session. The surgeon will allow the ERC to run until he or she feels the rod stop, signaling the maximum force to displace the spine has been reached.



MAGEC – SURGICAL TECHNIQUE

MAGEC SURGICAL TECHNIQUE

For a complete list of intended uses, indications, device description, contraindications, warnings, and precautions, please refer to the Instructions for Use (IFU) in the back of this technique guide.

STEP 1:
SURGICAL CONSTRUCT SELECTION

MAGEC rods are available in 4.5 and 5.5 mm diameters. Confirm an appropriate posterior fixation system is present to be implanted along with the rods.

Select the appropriate MAGEC rod configuration, based on the surgeon's desired distraction technique.

MAGEC ROD DISTRACTION TECHNIQUES

Tip: *It is imperative you understand your surgeon's desired distraction technique prior to MAGEC rod implantation. Once rods are implanted, only one distraction technique will be possible.*

Independent Distraction:

The ERC is able to independently control each magnet within each rod.

In this distraction technique, the ERC is able to control each rod independently from the other. This means the ipsilateral rod will distract when coupled with the magnets of the ERC while the contralateral rod will remain static. The ERC can then be moved to the contralateral side, and adjust that rod without interacting with the ipsilateral rod. This technique is applied if the surgeon does not want to get the same distraction growth out of the rods at the same time (e.g., focus distraction on the concavity).

For this distraction technique, one Standard Rod and one Offset Rod need to be implanted into the spine *(Fig. 1)*. The actuators within this rod configuration are designed to keep the magnets "offset" from one another.

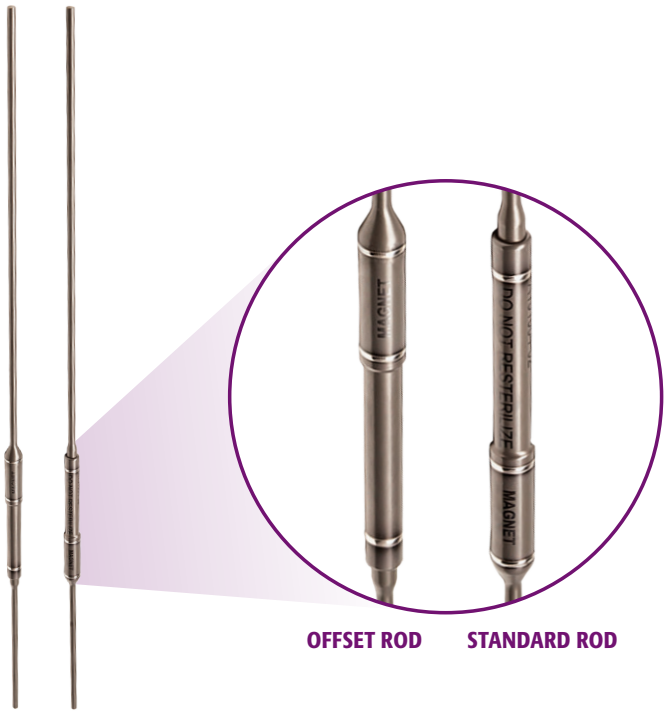
1. A Standard Rod can be identified as follows:
   With the "Cephalad" arrow pointing cephalad, the Standard Rod magnet is within the distal (inferior) portion of the actuator, and the rod telescopes at the proximal end of the actuator.
2. An Offset Rod can be identified as follows:
   With the "Cephalad" arrow pointing cephalad, the Offset Rod magnet is within the proximal (superior) portion of the actuator, and the rod telescopes at the distal end of the actuator.

Both rod types must be implanted with the "Cephalad" arrows pointing cephalad.

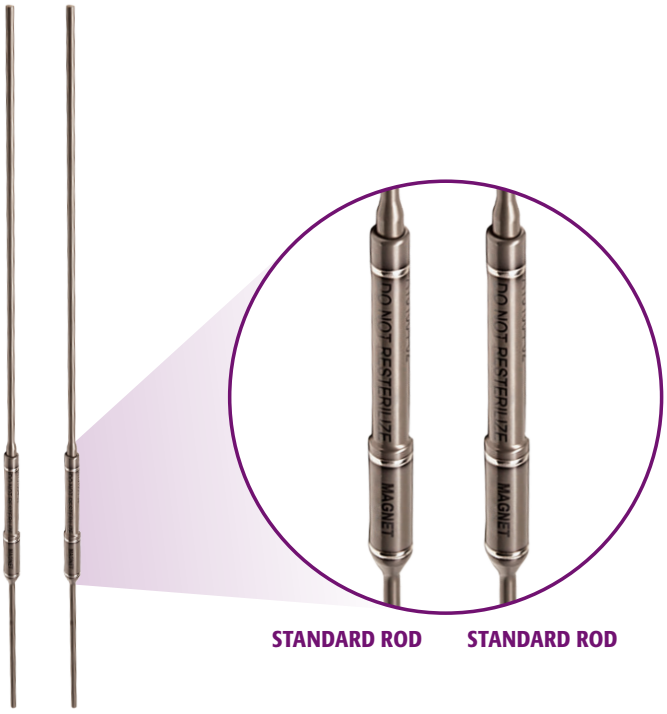
Coupled Distraction:

The ERC controls and adjusts the magnets within each rod simultaneously.

This distraction technique applies when two Standard Rods are implanted in the spine *(Fig. 2)*. In this technique, the ERC controls both rods simultaneously; the rods will distract and retract at the same time and to the same length.



(Fig. 1)



(Fig. 2)

STEP 2:
VERIFYING MAGEC ROD FUNCTIONALITY

Each MAGEC rod should be tested to verify distraction functionality prior to bending or cutting the rod.

1. Align the "Cephalad" arrows on the MAGEC rod and on the MAGEC Manual Distractor so that both arrows are facing cephalad. Slide the MAGEC Manual Distractor over the rod until it is coupled with the actuator magnet *(Fig. 3)*.
2. Turn the Manual Distractor four full rotations counterclockwise (follow the horizontal arrow marking), and visually confirm that the MAGEC rod is distracting *(Fig. 4)*.

Tip: *It may help to mark the rod at the end of the actuator to help visualize the manual distraction.*

3. Once distraction is verified, turn the Manual Distractor three full rotations clockwise to retract the rod back to its original state *(Fig. 5)*.

Tip: *More than three turns clockwise may jam the MAGEC rod distraction mechanism. If the rod becomes jammed, the magnetic force generated from the ERC is required to unjam it.*

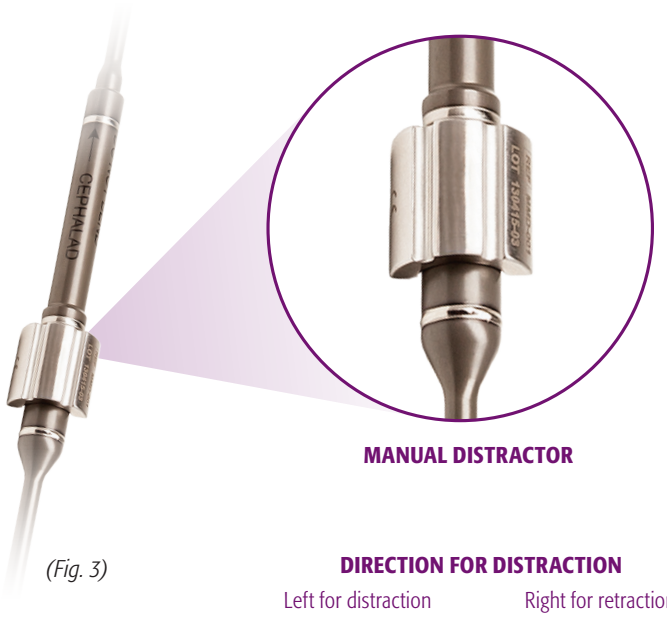
STEP 3:
MAGEC ROD CONTOURING AND INSERTION

Most MAGEC rods will be implanted through two mini-open incisions at the proximal and distal ends of the construct.

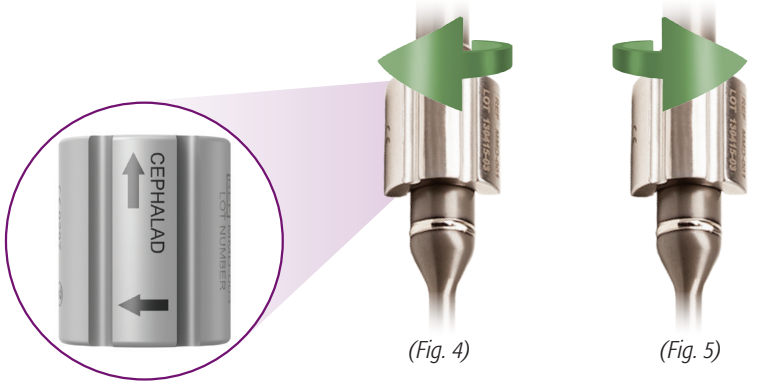
1. Place appropriate instrumentation (e.g., hooks and screws) at the proximal and distal anchor points of the construct.
2. Next, utilize a French Bender or Plate Benders to contour the MAGEC rod into the desired shape. Use a Rod Cutter to cut the MAGEC rod to the desired length.

Tip: *MAGEC rod templates are available for use prior to bending and cutting the implanted MAGEC rod.*

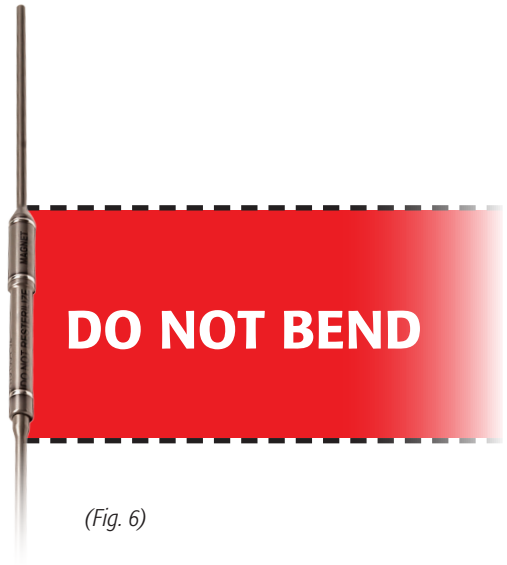
CAUTION
DO NOT BEND the actuator portion of the MAGEC rod *(Fig. 6)*. This will damage the distraction mechanism, and may prevent the rod from functioning postoperatively. It is suggested to mark a 10mm "buffer zone" proximally and distally around the actuator to ensure no bend reaches the actuator.



(Fig. 3)



(Fig. 4) *(Fig. 5)*



(Fig. 6)

MAGEC SURGICAL TECHNIQUE

STEP 3:
MAGEC ROD CONTOURING AND INSERTION (CONT.)

3. After bending the MAGEC rod, re-verify that the distraction mechanism was not compromised. Repeat Step 2 with the MAGEC Manual Distractor to verify actuator integrity.

4. Rods with any sagittal bends should be rotated into the coronal plane when passed subfascially to prevent risk of damage to the spinal cord and/or surrounding tissue. Once the rod is visible within the proximal and distal exposures, rotate the rod back into the sagittal plane utilizing a rod gripper.

Tip: *Some surgeons use a chest tube to pass the rod subfascially to prevent tissue damage.*

5. It is suggested to verify the actuator locations with fluoroscopy prior to locking down the construct. Actuator profiles should be parallel to help minimize the flat portion of the rod within the spinal construct.

Tip: *Surgeons typically place the actuator(s) at the thoracolumbar junction of the spine, which is anatomically flatter than other regions.*

6. Provisionally lock down the MAGEC rod with appropriate lock screws.

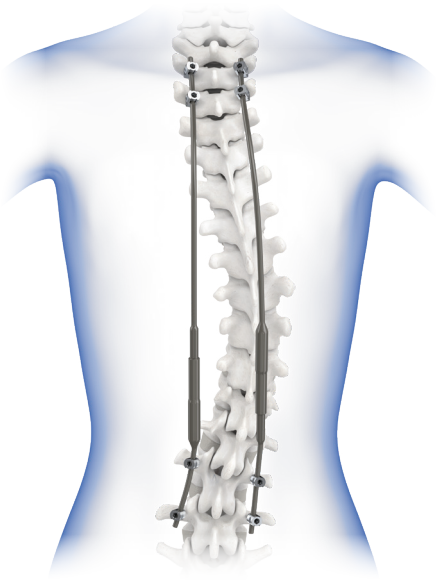
7. Distraction may be applied to the construct at this point.

8. Utilize a torque T-handle, final driver, and counter-torque to final-tighten the lock screws, and lock down the construct *(Fig. 7)*. Next, prepare the distal, or proximal and distal, instrumented vertebrae for fusion. NuVasive® bone grafts and/or autograft may be used to promote fusion.

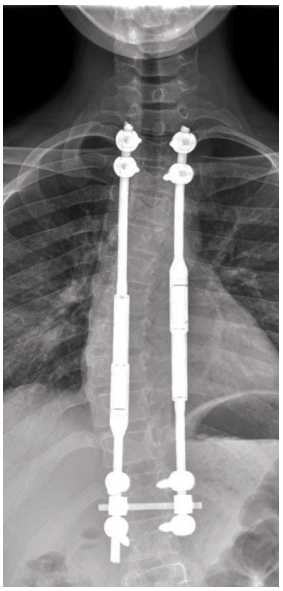
9. Take a final fluoroscopy image to confirm desired implantation of the MAGEC rods prior to closing the incisions *(Fig. 8)*.

IMPLANT REMOVAL:

To remove the MAGEC rod, first loosen and remove any lock screws utilizing a lock screw driver, counter-torque, and T-handle. Once all of the lock screws have been removed from the screw tulips, grasp the rod with a Rod Holder and lift up to remove it from the screw heads. Repeat on the contralateral side (if needed).



(Fig. 7)



(Fig. 8)

FINAL CONSTRUCT

MAGEC – DISTRACTION TECHNIQUE

MAGEC DISTRACTION TECHNIQUE

The following technique presents a standard MAGEC distraction protocol for a patient implanted with a Standard and an Offset Rod construct. The technique also presents some alternative patient positioning techniques that may be used to further facilitate a MAGEC distraction procedure. The procedure is shown using the ERC.

The following equipment is required for a distraction *(Fig. 1)*:

- Pillow
- Felt-Tip Marker
- MAGEC Wand
- MAGEC External Remote Controller (ERC 1 or 2)

STEP 1:

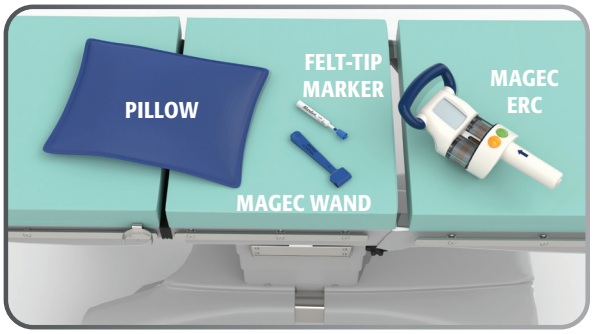
PATIENT SETUP

1. Have the patient remove any thick clothing (like sweaters or jackets) that may be covering the implant area. A thin, non-metallic shirt is fine.
2. Have the patient remove any loose metal objects (e.g., belt buckles, jewelry, cell phones, keys, etc.).
3. Lay the patient face down on a non-magnetic examination table.
4. Some surgeons cover the implant magnet area with a drape.

STEP 2:

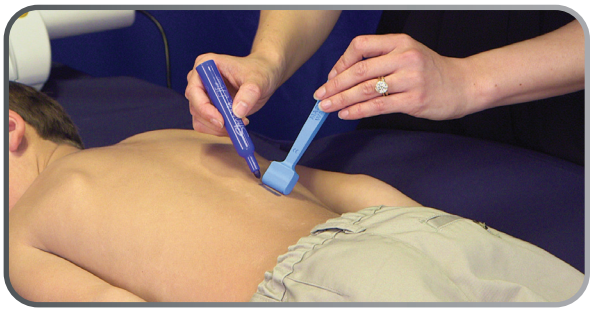
IDENTIFY ACTUATOR MAGNET LOCATION WITH THE MAGEC WAND

1. Hold the MAGEC Wand vertically by the thumb/forefinger grip on the device *(Fig. 2)*. Glide the MAGEC Wand magnet up and down above the surface of the skin, approximating the location of the internal magnet in the MAGEC actuator. The MAGEC Wand magnet will pull to the strongest point of attraction and align itself parallel with the internal magnet.
2. Mark the location of the Standard Rod magnet in a Standard/Offset Rod configuration. A felt-tip pen is utilized *(Fig. 3)*.
3. Mark the location of the Offset Rod magnet in a Standard/Offset Rod construct, or the second Standard Rod magnet in a Standard/Standard Rod construct *(Fig. 4)*.

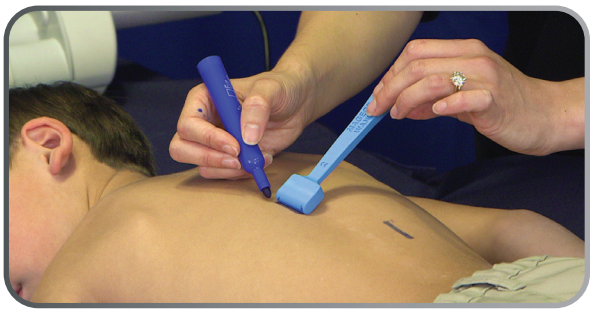


(Fig. 1)

(Fig. 2)



STANDARD ROD MAGNET LOCATION *(Fig. 3)*



OFFSET ROD MAGNET LOCATION *(Fig. 4)*

STEP 3:

EXTERNAL REMOTE CONTROLLER (ERC) SETUP

1. Plug the Power Cord into the Power Supply.

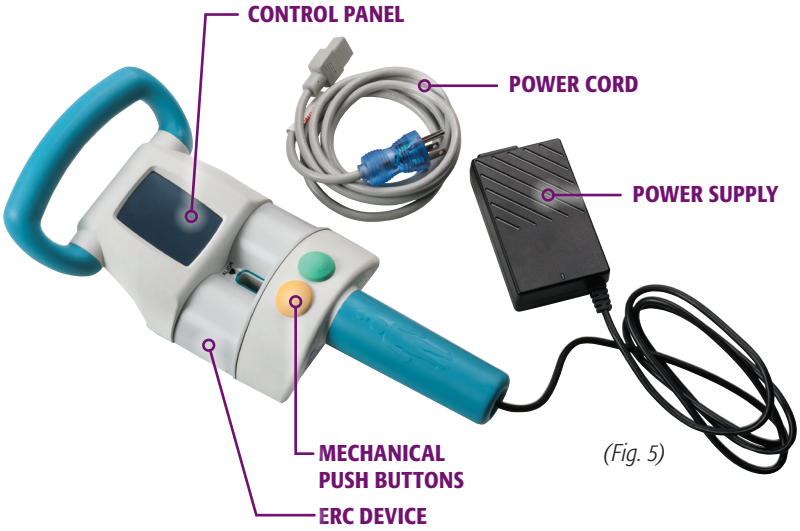
2. Remove the ERC from its case only when ready for use. Plug the ERC Power Cord into an accessible and appropriate power outlet close to the patient.

WARNING
Never place the ERC near electronic media or appliances. The strong magnetic field may damage magnetic media (such as cell phones, tablets, DVDs, DVD players, desktops, laptops, etc.).

CAUTION
Use only the supplied Power Cord or an equivalent hospital-grade cord rated for 10 amps minimum. Replacement power cords are available from NuVasive Specialized Orthopedics.™

WARNING
The ERC 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; jewelry, watches, keys, and cellular phones, etc. 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.

CAUTION
The ERC should be placed immediately over the area of the patient's body only at the magnetic portion of the MAGEC implant. Do not place the ERC near any other parts of the body that may have implants containing ferromagnetic material.



(Fig. 5)

MAGEC DISTRACTION TECHNIQUE

STEP 3:
EXTERNAL REMOTE CONTROLLER (ERC) SETUP (CONT.)

3. Select the desired distraction mode: Target or Continuous. It is suggested to use Target Mode if the surgeon wants to follow growth (distract only a specified amount), and Continuous Mode if the surgeon wants to drive growth (distract as much as possible). The ERC start-up screen defaults to Target Mode *(Fig. 6)*.

Tip: *The distraction reading on the ERC assumes the magnets in the machine are optimally coupled with the magnets in the implant. There may be a slight variation between actual distraction and the distraction displayed on the ERC if the implant and ERC are not optimally coupled.*

Target Mode:

Target Mode allows the user to adjust the MAGEC rod to a fixed distance. If a positive target value is set, the ERC will automatically stop when the implant has extended to the targeted value.

The target value can be set in two ways:

1. Pressing the "+" button will increase the target distraction value by .1mm. Pressing the "-" button will decrease the target value by .1mm *(Fig. 7)*.

2. Press the "#" button to bring up a numeric keypad screen *(Fig. 8)*. The keypad screen enables the user to directly input the target distraction value. To change or correct the target value, first press the "ZERO" button to zero out any current target value. After the desired value has been entered, press the "Accept" button to confirm targeted value, and return the display screen to the Target Mode main operating screen *(Fig. 7)*.

Tip: *The ERC does not support targeted retraction in Target Mode. The retraction "-" button is visible only when a positive target value is entered, and if pressed, it will run retraction in Continuous Mode.*

Continuous Mode:

Continuous Mode allows the ERC to run as long as the Extend or Retract Push Buttons are held. There is no input value that will instruct the ERC to stop running.

The value displayed above "Continuous Mode" increases or decreases as the implant is adjusted. Pressing the button labeled "MODE" on the Target Mode operating screen toggles the main operating screen from Target Mode to Continuous Mode *(Fig. 9)*.

(Fig. 6)

(Fig. 7)

(Fig. 8)

(Fig. 9)

STEP 4:

EXTERNAL REMOTE CONTROLLER (ERC) DISTRACTION

1. Position the Alignment Window of the ERC over the marked implant magnet area on the skin. The ERC should be oriented along the axis of the implant with its Orientation Arrow pointing toward the patient's head.

2. Hold the ERC against the patient over the implant *(Fig. 10)*.

Tip: *The ideal coupling force of the ERC and MAGEC rod magnet is achieved when the ERC magnets are 10mm away (or less) from the implanted magnet.*

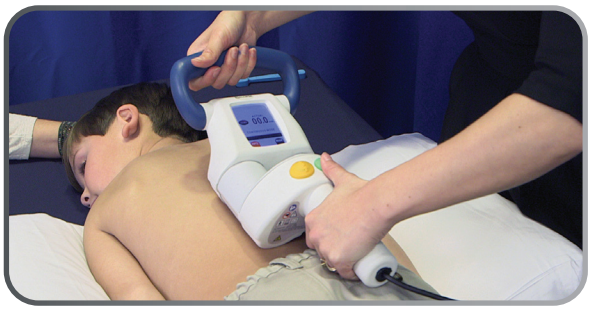
3. Press the Extend (green) or Retract (yellow) Push Button, as needed, to adjust the implant.

Tip: *Parents are encouraged to provide comfort during distraction procedures to help their child stay calm during rod lengthening. It is important that patients stay as still and relaxed as possible (Fig. 11).*

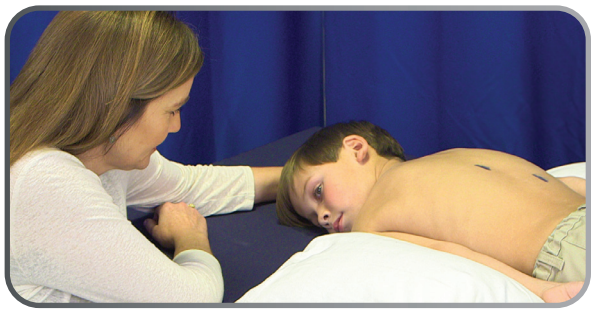
Tip: *Alternative ERC positioning is possible with challenging anatomy. Position one of the ERC magnets directly over the implanted rod magnet (Fig. 12).*

4. After adjustment, always confirm the amount of distraction by ultrasound *(Fig. 13)* or x-ray *(Fig. 14)* imaging.

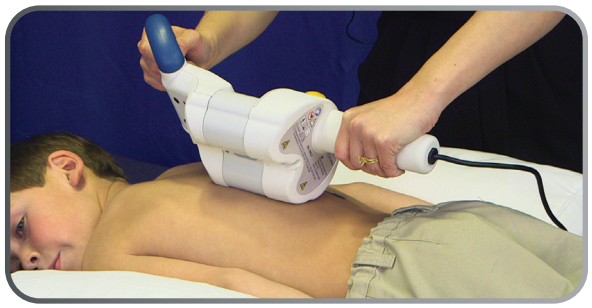
CAUTION
If retraction of the device is needed, never retract the device more than the amount lengthened during the preceding lengthening session. Failure to follow this caution may result in pulling biologic material that may have adhered to the rod into the internal space of the actuator.



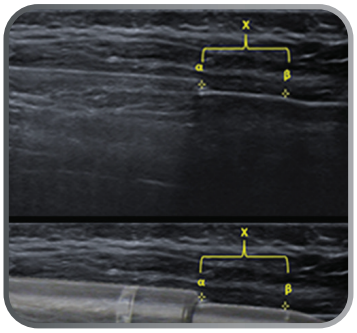
(Fig. 10)



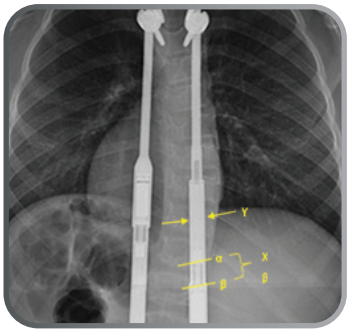
(Fig. 11)



(Fig. 12)



(Fig. 13)



(Fig. 14)

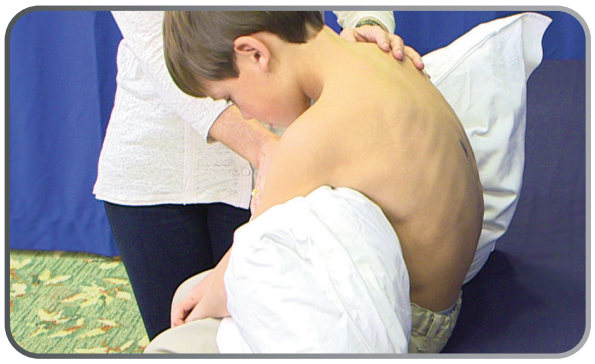
MAGEC DISTRACTION TECHNIQUE

ALTERNATE METHODS

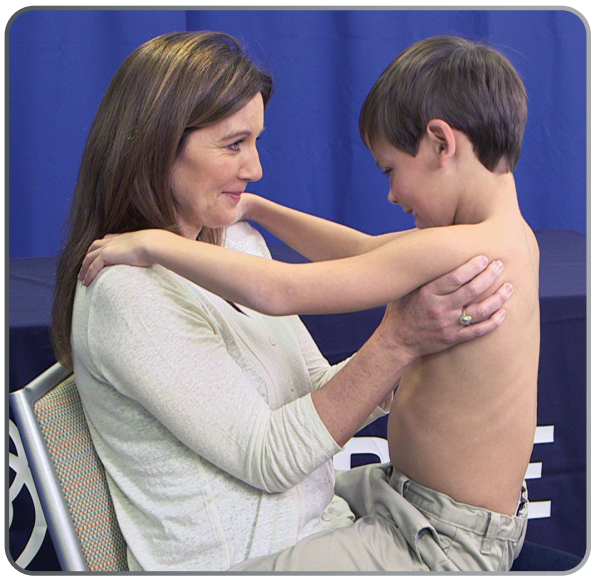
Patient Positioning:

1. Alternative patient position: fetal position – tuck knees and head into chest *(Fig. 15)*.
2. Alternative patient position: pillow hug *(Fig. 16)*.
3. Alternative patient position: sitting on parent's lap. Parents can help offload rods slightly by lifting patient under arms *(Fig. 17)*.

(Fig. 15)



(Fig. 16)



(Fig. 17)

ALTERNATE METHODS (CONT.)

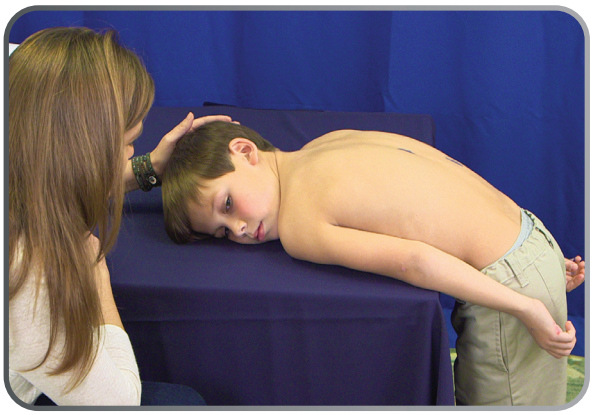
Patient Positioning:

4. Alternative patient position: bending over a table's edge *(Fig. 18)*.

5. Alternative patient position: manual Traction Technique – a gentle pulling force can be applied to a patient's pelvis or legs *(Fig. 19)*.

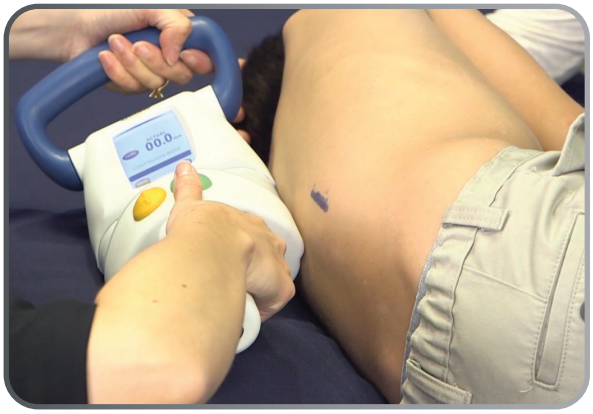
Note: *Surgeon supervision required during technique.*

6. Alternative ERC positioning when distracting a patient in the fetal position *(Fig. 20)*.



(Fig. 18)

(Fig. 19)



(Fig. 20)

CATALOG

MAGEC STANDARD IMPLANTS

DESCRIPTION	INTL CATALOG #
4.5mm Standard Rod with 70mm Actuator	RA002-4545SL70
4.5mm Offset Rod with 70mm Actuator	RA002-4545SLR70
4.5mm Standard Rod with 90mm Actuator	RA002-4545SL
4.5mm Offset Rod with 90mm Actuator	RA002-4545SLR
5.5mm Standard Rod with 70mm Actuator	RA002-5555SL70
5.5mm Offset Rod with 70mm Actuator	RA002-5555SLR70
5.5mm Standard Rod with 90mm Actuator	RA002-5555SL
5.5mm Offset Rod with 90mm Actuator	RA002-5555SLR

MAGEC INSTRUMENTS

DESCRIPTION	CATALOG #
MAGEC ERC1	MAGECERC1
MAGEC ERC2	MAGECERC2
MAGEC Rod Template, 70mm	MR2-4070T
MAGEC Rod Template, 90mm	MR2-4090T
MAGEC Wand	MML-001
MAGEC Manual Distractor	MMD-003

MAGEC SPINAL BRACING AND DISTRACTION SYSTEM INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION:

The NuVasive, Inc. MAGEC System is comprised of a sterile, single use spinal rod that is surgically implanted using appropriate commercially available fixation components (i.e. pedicle screws, hooks and/or connectors). The system includes a non-sterile hand held External Remote Controller that is used at various times after implant to non-invasively distract (lengthen) 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 device to be lengthened by use of the External Remote Controller. The rod is implanted and secured using standard fixation components.

The hand held non-invasive External Remote Controller is electrically powered. The device is placed over the patient's spine and then manually activated, which causes the implant magnet to rotate and lengthen 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 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 infection or pathologic conditions of bone which would impair the ability to securely fix the device (e.g. osteoporosis, osteopenia).
- Metal allergies and sensitivities.
- Patient with a pacemaker or other active, electronic devices (e.g. ICD).
- Patients younger than two years old.
- Patients weighing less than 25 lb. (11.4 kg)
- Patients and/or families unwilling or incapable of following postoperative care instructions.
- Patients with stainless steel wires or other implants containing incompatible materials.
- 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 which may lead to delays in surgery (leading to additional blood loss and extended exposure to anesthesia), inability to complete the procedure and/or cancellation of the procedure, or may result in pain, suboptimal correction, and/or necessitate revision surgery.
- Failure to follow the MRI Safety Conditions may result in diagnostic delays, stalls or malfunctions of active implantable devices, malfunction of the MAGEC rod, or tissue damage.

WARNINGS

- 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 System 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 System Rods are supplied sterile and are for single use only. The implant has not been tested to be cleaned or sterilized for multiple uses. If the implant is used more than once, the device may not be sterile and could cause a serious infection.
- Do not use implant if the sterile packaging has been damaged or is open.
- 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 (ERC – OM0000; ERC2 – OM0006) for operation of the External Remote Controller.
- Confirm 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.

PRECAUTIONS

- During period of implant, if brace is used on patient, brace should not have any magnetic metallic components (steel, etc.) which may affect the implanted magnet.
- During the implantation period, patient should not participle in contact or severe sports, or other high risk activities.
- During the implantation period, patient should limit their backpack weight to 20 lb. (9 kg) or less.
- Ensure that a sufficient curve is placed on bendable portion of rod to conform to desired sagittal curve.
- The longer portion of rod (as packaged) should always be oriented cephalad (proximally) on patient when implanted (see Fig. 5).
- Patients should be limited to those having a BMI (body mass index) of 25 or less.
- Rod should always be used in compression, not in tension.
- Examine the implant carefully prior to use and use the MAGEC Manual Distractor to confirm 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 Fig. 5).
- This device is for prescription use only by the order of a physician.
- Device should be removed after implantation time of no more than two years.

INSTRUCTIONS FOR USE

PRECAUTIONS (CONT.)

- Device should be removed if skeletal maturity has been reached (e.g. closed tri-radiate cartilage; skeletal maturity as defined by Risser Sign).
- Device should be removed after active distraction period has ended.
- Device should be removed or replaced if maximum distraction length of the device has been attained, and patient is not skeletally mature (e.g. open tri-radiate cartilage; skeletal maturity as defined by Risser Sign).
- Utilize extreme caution when handling instruments made from magnetic materials such as stainless steel in proximity of the magnet of the actuator, as similar materials will be attracted to each other.
- When cutting the rod to the desired length, take care not to leave any sharp burrs at the site where the rod is cut.
- Do not bend the actuator.
- Do not repeatedly bend or excessively bend the rod. The rods should not be reverse bent in the same location.
- If retraction of the device is needed, never retract device more than the amount lengthened during the preceding lengthening session. Failure to follow this caution may result in pulling biological material that may have adhered to rod into internal space of actuator.
- Follow External Remote Controller (ERC) Operator's Manual and MAGEC Technique Guide to confirm proper alignment between the ERC and magnet of the actuator.
- After two years implantation time, continued implantation may increase the rate of adverse events or complications.

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.

NOTES

To order, please contact your NuVasive Sales Consultant or Customer Service Representative today at:
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