MAGEC SPINAL BRACING AND DISTRACTION SYSTEM

INSTRUCTIONS FOR USE

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

Product Description:

The NuVasive, Inc. **MAGEC Spinal Bracing and Distraction System** is comprised of a sterile single use spinal rod that is surgically implanted using appropriate NuVasive Reline and Armada fixation components, or Stryker Xia fixation components (i.e., pedicle screws, hooks and/or connectors, provided non-sterile, to be sterilized by the end user). 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 implant 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 with severe progressive spinal deformities (e.g., Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) secondary to early-onset scoliosis 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:

- Patients with 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).
- 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 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 following warnings are associated with the implant component of the MAGEC System:

- The MAGEC System (including non-invasive distraction procedures using the ERC 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 Spinal Bracing and Distraction System rods are supplied sterile and are for single use only. The implant has not been tested to and cannot 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 ERC Operator's Manual (ERC 1 – OM0000; ERC 2 – OM0006) for operation of the ERC
- 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.

The following warnings are associated with the ERC component of the MAGEC System:

- Always confirm the predicted implant adjustment length displayed by the ERC with x-ray or ultrasound measurements.
- This equipment is intended for use by healthcare professionals only.
- 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. 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 ERC 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:

Patient-related Precautions

- Proper patient selection is essential to ensure optimal performance and function of the device and to minimize potential adverse events and complications. Surgeons should take into consideration the patient's weight and/or body mass index (BMI) as larger and heavier patients may experience higher device wear, potentially leading to additional adverse tissue response.
- Patients should be limited to those having a BMI (body mass index) of 25 or less.

Intraoperative Precautions

- 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 Figure 1 and Figure 2).
- Ensure a sufficient curve is placed on the bendable portion of the rod to conform to the desired sagittal curve.
- 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.
- 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.

Postoperative Precautions

- 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, patient should not participate in contact or severe sports or other high risk activities.
- During the implantation period, the patient should limit carried weight to 20 lbs. (9 kg) or less.
- The MAGEC rod should always be lengthened to distract the spine. The rods should not be used to shorten or compress the spine.
- 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 (as defined by the Risser Classification).
- Device should be removed or replaced if maximum distraction length of the device has been attained even if patient is not skeletally mature (as defined by the Risser Classification).
- 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 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.

The following precautions are associated with the ERC 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 ERC or shielding the location.
- Only use the ERC 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 A minimum. Replacement power cords are available from NuVasive Specialized Orthopedics, Inc.
- The ERC 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 ERC near any other parts of the body, for example, portions of the body which may contain ferromagnetic material containing implants. When the ERC is not being actively used on the patient, it should always be kept within its protective case.

Details of the MAGEC System:

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.

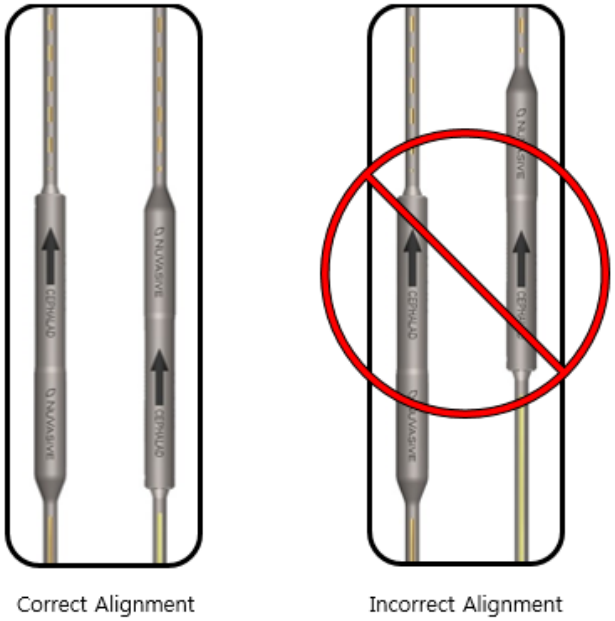


Figure 1: Standard/Offset Dual Rod Combination

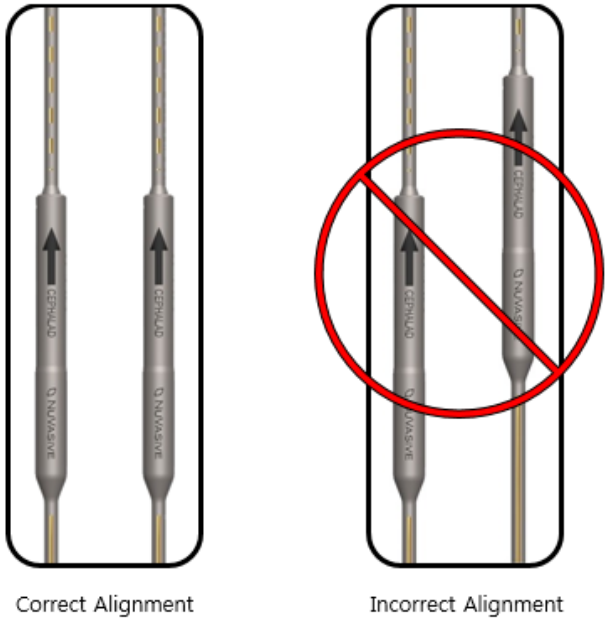


Figure 2: Dual Standard Rod Combination

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: that 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 (for MMD-003):

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

Distraction Test Procedure:

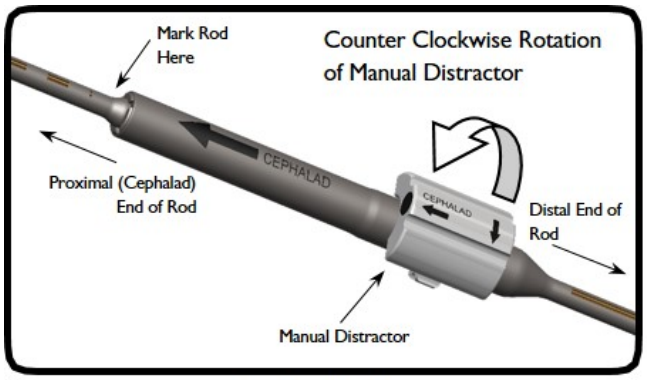
1. For the sterile packed MAGEC Manual Distractor (MMD-003), ensure that the MAGEC Manual Distractor is in its original package.

2. After the MAGEC rod 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."

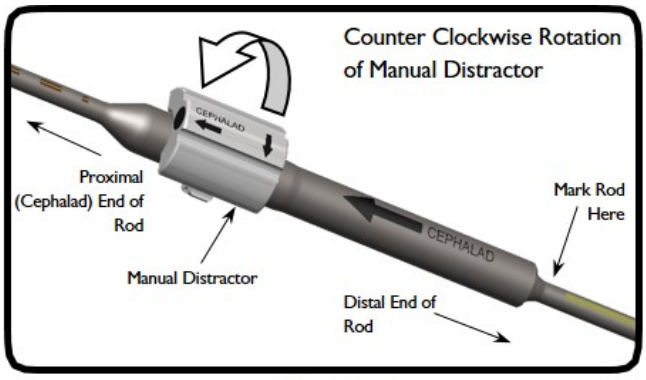
3. Rotate the MAGEC Manual Distractor, by hand, about the centerline axis of the actuator counterclockwise when viewed from the distal end of the implant with the arrow pointed up (cephalad). This will cause the implant to distract (lengthen).

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.**

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 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, Inc. following instructions provided. Please call **1-855-435-5477** 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 ERC.
- Please refer to the MAGEC packaging label for the expiration date of the implantable device.

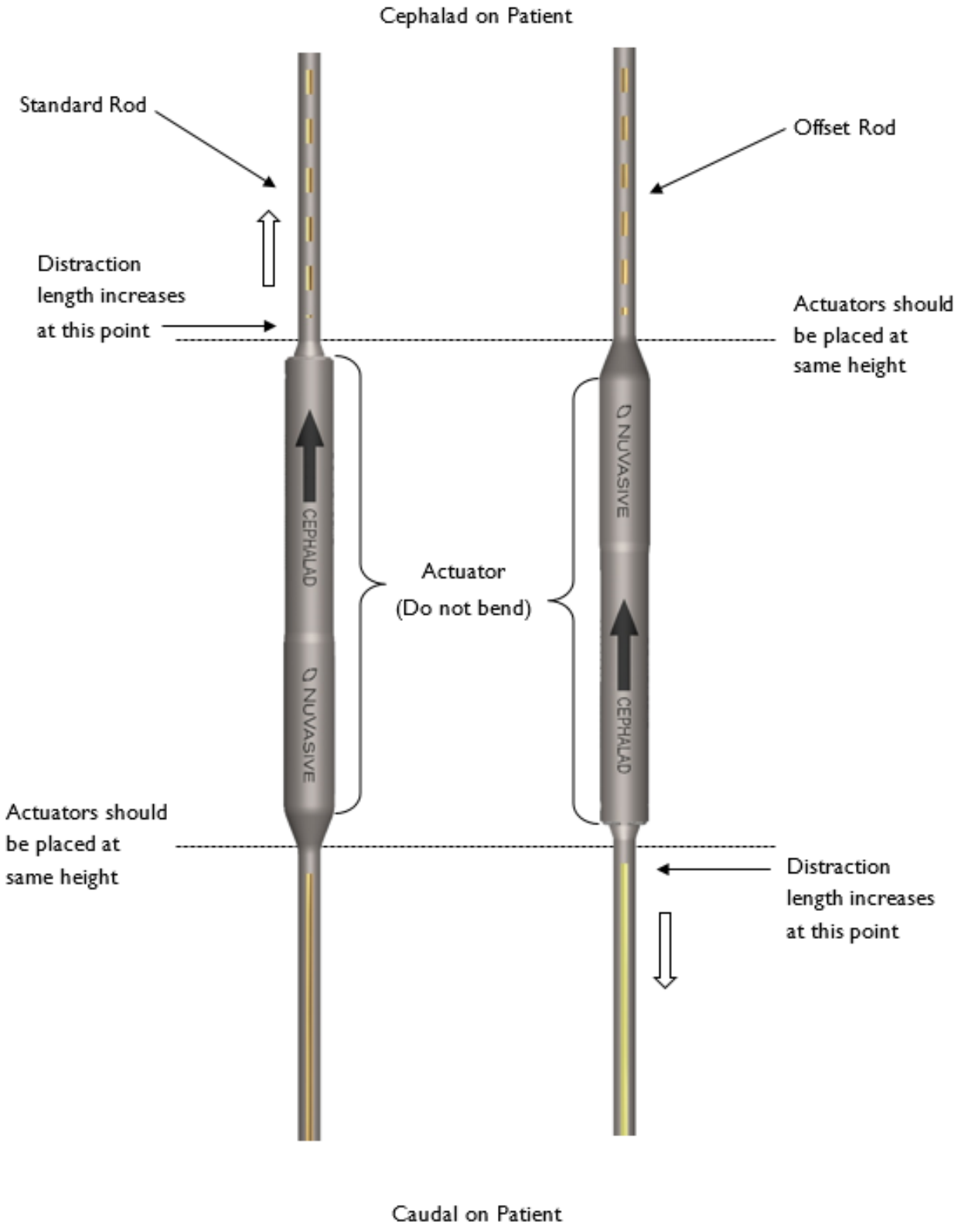


Figure 3: Dual Rod

For Symbols Glossary, please refer to https://www.globusmedical.com/eifu/symbols-glossary/

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