Clinical Commissioning Policy:

Non-Invasively Lengthened Spinal Rods for Scoliosis

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NHS England

Clinical Commissioning Policy: Non-Invasively Lengthened Spinal Rods

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Document Status

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Policy Statement

NHS England will commission in accordance with the criteria outlined in this document.
In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.
This policy document outlines the arrangements for funding of this treatment for the population in England.

Safety Notice (April 2020)

NuVasive has undertaken voluntary action to suspend the supply of all MAGEC rods to the UK to address concerns identified by MHRA over the continued use of the device. This action is described in the Field Safety Notice issued by the manufacturer dated 01 April 2020.

MHRA issued a Medical Device Alert which addressed the need for additional clinical follow-up in relation to the MAGEC Model X following the manufacturer's Field Safety Notice dated 13 February 2020.

The MHRA have advised clinicians/provider organisations:

- Do not implant MAGEC rods in the UK until further notice.
- Identify all patients implanted with a MAGEC System and ensure systems are in place to follow up these patients.

The MHRA have confirmed that their advice applies to all MAGEC systems (i.e. all versions) and states that no MAGEC rods are to be implanted in the UK until further notice. The supply of MAGEC Systems will continue to be suspended while the investigation is ongoing.

However, the MHRA do acknowledge that there may be some rare cases where a MAGEC rod may be deemed clinically essential by the Clinician. In such cases, a specific request is required to be undertaken by the manufacturer, with the support of the Consultant, to MHRA for the approval for use of the device in that specific case. These cases will be carefully considered by the MHRA Devices Clinical Team.

Equality Statement

Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.

Plain Language Summary

Scoliosis is a medical condition in which a child's spine is curved to the side. Currently, there are four main types of treatment: casting, bracing, insertion of growth rods and spinal fusion. A small group of children will not benefit adequately to treatment such as observation, bracing and spinal fusion as they either fail to prevent curve progression and results in a greatly reduced chest function resulting in early respiratory failure and mortality. In such patients, spinal instrumentation can be used to partially correct the curve whilst maintaining spinal growth. These fall into 2 categories- growing systems and lengthening systems. Lengthening systems consists of spinal rods which can be lengthened surgically or non-invasively. A review of the evidence on the clinically efficacy, safety and cost-effectiveness of non- invasive lengthening systems was undertaken. Based on the findings of the review, this policy states that NHS England will fund treatment of scoliosis for children meeting the criteria defined.

Please note above Safety Notice (April 2020).

1. Introduction

Scoliosis is a lateral curvature of the spine associated with rotation. Curves progress during growth and can affect lung function resulting in cardiorespiratory morbidity and early mortality especially if the scoliosis started before the age of 5 years or if the curve becomes large. There are four main types of treatment: casting, bracing, insertion of growth rods and spinal fusion. The traditional treatment for scoliosis is to partially correct the curve using instrumentation and fuse the spine in the new position. However, in young patients this results in a short spine and a reduction in thoracic volume and lung function which produces cardiorespiratory morbidity. To prevent this problem, spinal instrumentation has been developed to allow partial correction of the curve whilst maintaining spinal growth. These systems fall into 2 categories:

1. Growing systems: The instrumentation is inserted and is designed to allow growth (Luque trolley, Shilla procedure). A definitive instrumented spinal fusion is usually required once growth has finished. These systems do not allow 'normal' growth with estimates from 40-75% of normal growth.
2. Lengthening systems: The instrumentation is inserted and designed to be lengthened at defined time-points until growth has finished. A definitive instrumented spinal fusion is then required. Until recently the lengthening was performed in theatre every 6 months involving a surgical procedure and a one night stay in hospital and short period of recovery. This proves disruptive for the child and family and compliance with lengthening is affected. Non- invasively lengthened spinal rods allow for outpatient lengthening every 3 months using an external magnet and are more popular with the child and their family.

This is a very rare but important group as inadequate treatment such as observation, bracing and spinal fusion either fails to prevent curve progression and results in a greatly reduced chest function (restrictive pattern) resulting in early respiratory failure and mortality. Unfortunately, surgical treatment has a high risk of complications.

1. What are the advantages?

The main advantage is the avoidance of repeated surgery every 6 months to lengthen the rods requiring a general anaesthetic, time off school to recover from the procedure and disruption and stress to the patient and family.

A reduced infection rate is expected as surgical lengthening involves exposing

the instrumentation which is obviously not required for non-invasive lengthening.

2. What are the disadvantages?

The rods allow only 48mm of growth before they require changing which requires a moderate sized surgical procedure (not as large as the initial insertion as the screws and hooks in the bone can be re-used).

The cost of the rods is significantly higher than the rods which are lengthened surgically but it has been shown that the saving of the additional theatre procedures to lengthen the rods offsets this initial cost (see below).

Patients cannot have an MRI scan with the rods in-situ.

There is no long-term data for these rods, and it is therefore proposed that all patients who have this procedure are entered onto the British Spine Registry (see above). This will be the currency for this procedure with funding being linked to data entry.

3. What are the indications and contra-indications?

See Appendix 1 which also describes the technique for insertion.

The technique is expensive and relies on the production of spinal height which would not be gained with a spinal fusion. Therefore, there must be a significant amount of spinal growth potential remaining to justify the additional surgery and expense over a spinal fusion. Whilst skeletal age is the best measure of remaining growth, this is not recorded by NHS data collection systems so we have to use chronological age and allow surgeons an appeal process through the IFR mechanism for patients whose skeletal age may be younger than their chronological age. It is suggested that the age range should be restricted to 2-11 years in girls and 2-13 years in boys due to the later skeletal development of boys compared to girls. Radiological bone age within the accepted chronological age limits should be accepted as sufficient evidence to justify use of these rods.

To justify revising the rods once they have reached their maximum 48mm excursion, there must be at least 4cm of remaining growth potential otherwise a revision to a fusion is probably the best option.

4. Where should the procedure be performed?

There is no difference between this procedure and other procedures for paediatric spinal deformity as in the existing D14 service specification.

5. How often and by how much should the lengthenings be?

The lengthenings should be performed every 4-16 weeks and further research is required to determine the optimal technique for lengthening (limited amount or maximal to clunk). Currently, 3 monthly lengthenings are most common. Work should be done to look at alternatives to radiographs to determine the amount of lengthening performed as this exposes the patient to additional radiation. Ultrasound may be possible. Lengthening frequency is not associated with complications but obviously needs to be performed as this is the aim of the treatment.

6. How often are these rods used in England?

Excluding the rods inserted in private hospitals 162 rods have been inserted in 91 patients in England between April 2012 and August 2013, suggesting approximately 114 rods per year. This number is likely to increase as children require revision rods inserting.

Two rods are usually used as single rods have a higher failure rate in traditional surgically lengthened rods, especially in ambulant children. The indications for single rods need to be evaluated.

2. Definitions

Scoliosis is a medical condition in which a person's spine is curved to the side. Although it is a complex three-dimensional deformity, on an X-ray, viewed from the rear, the spine of an individual with scoliosis can resemble an "S" or a "?", rather than a straight line.

Scoliosis is typically classified as either congenital (caused by vertebral anomalies present at birth), idiopathic (cause unknown, sub-classified as infantile, juvenile, adolescent, or adult, according to when onset occurred), or secondary to a primary condition.

3. Aim and objectives
This policy aims to:

- Specify the clinical circumstances whereby NHS England will commission or not commission non-invasively lengthened spinal rods for scoliosis.

The objectives are to:

- Clarify how the evidence determines the clinical commissioning position of NHS England -invasively lengthened spinal rods for scoliosis.

4. Epidemiology and needs assessment
In the UK, scoliosis affects 3 to 4 children out of every 1,000 (0.03 to 0.04 per 100,000) and can develop at any time during childhood and adolescence. In 90 percent of cases of childhood scoliosis, treatment is not required since the condition corrects itself with age. Most of the remaining 10% of children with scoliosis can be successfully treated using a back brace to prevent progression of the spinal deformity. Approximately 1 in 350 children with scoliosis require surgery to correct the curvature of their spine, equivalent to around 90 children per year in England.

5. Evidence base

Clinical Effectiveness: At present the available evidence is from one (unpublished) matched case series on the MAGEC system and published and unpublished case series.

- One published retrospective case series on the Shilla growth guidance technique was identified (n=10; minimum follow-up two years) (McCarthy 2014). This study reported mean improvements in coronal correction, truncal height and the space available for the lungs. However, there is currently insufficient evidence to draw any conclusions about the effectiveness of the Shilla technique in itself or in comparison to magnetically lengthened growing rods or conventional growth rods.
- Published evidence for the clinical effectiveness of magnetically lengthened growing rods comes from three prospective case series Akbarnia 2013, Dannawi

2013, Cheung 2012) (n=34,14 and 5 respectively; mean follow-up range 10 to 19 months). Two further unpublished studies were included in the NICE assessment of the MAGEC system: a retrospective review (n=30; mean follow-up 21 months) and a retrospective matched case series of patients who received treatment with the MAGEC system (n=12; mean follow-up 2.5 years) and patients who received conventional growth rods (n=12; mean follow-up 4.1 years) (Akbarnia 2013b , Ellipse 2013).

- The published prospective case series and the unpublished retrospective review all demonstrated improvements in mean Cobb angle[1] and spinal height following treatment with the MAGEC system. In the unpublished matched case series the post-operative mean increase in spine height was statistically significantly greater for conventional growth rods (41mm) compared to MAGEC (18mm), however, there was little difference between mean changes in Cobb angle for MAGEC and conventional growth rod patients and there was no statistically significant difference in mean annual total spine growth between the treatments.
- NICE performed a meta-analysis of the MAGEC system and conventional growth rods as part of their assessment of the MAGEC system; however, they concluded that the high heterogeneity between studies limited the usefulness of the meta-analysis results.
- In the NICE analysis the mean number of surgical procedures per patient was lower for the MAGEC group (1.2) than for a conventional growth rod group with shorter follow-up (<38 months) (4.3) and a conventional growth rod group with longer follow-up (≥38 months) (5.8).

Cost Effectiveness: No published studies assessing the cost-effectiveness of non-invasively lengthened spinal rods were identified.

Safety: In the one unpublished matched case series the conventional growth rod group had a higher number of implant-related complications, non-implant-related complications and surgical site infections than the MAGEC group. Significance tests were not reported.

[1] A measurement for the magnitude of the spinal curves

6. Rationale behind the policy statement

This policy is based on the findings of an evidence review by Solutions for Public Health and cost-effectiveness analysis by the CRG assisted by an independent financial analysis commissioned by NHS England.

7. Criteria for commissioning

From the evidence presented above, non-invasively lengthened spinal rods will be commissioned by NHS England for children with scoliosis who meet the following criteria:

- Consultant Paediatric Spinal Surgeon feels that an instrumented spinal fusion will result in an unacceptable reduction in final height and respiratory function AND
- Between the ages of 2 and 11 for girls and 2 and 13 for boys. Some children are not as skeletally mature as their chronological age so a radiograph confirming bone age within the acceptable age limits is satisfactory. Use outside the specified chronological and skeletal age range may be appropriate if the patient is particularly small for age, has late development or has an increase in respiratory risk but a request should be submitted through the IFR process.

The Consultant will decide which of the available growing systems should be used after consideration of the aims of treatment and the risks in consultation with the family.

Exclusions (see Appendix 1):

• Infection or Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
• Metal allergies and sensitivities.
• Patient with Pacemaker
• Patient requiring MRI imaging during the expected period device will be implanted
• Patients younger than two years old.
• Patients weighting less than 25 lb. (11.4 kg)
• Patients and/or families unwilling or incapable of following postoperative care instructions.

The device must be used as advised by the implant manufacturers (see Appendix 1).

The currently available device allows lengthening of 48mm at which point the clinician must calculate the anticipated normal growth over the instrumented segment of the spine to decide whether to revise the rods to allow further lengthening or to perform a definitive fusion. Anticipate growth must exceed 4cm to justify a revision of the Magec rods rather than a definitive fusion

The scientific evidence for surgically lengthened growing rods is good but the evidence for non-invasively lengthened growing rods is limited. An NIHR funded clinical trial is still recruiting (http://clinicaltrials.gov/show/NCT01362881 . NICE is also currently reviewing this treatment and this policy statement will be reviewed following the NICE review (http://guidance.nice.org.uk/MT/169). Due to the lack of long-term evidence, all patients should be consented and entered into the British Spine Registry (BSR) which will be designed to record:

1. Details on patient diagnosis, chronological and skeletal age
2. Implants inserted
3. Surgeon and Hospital
4. Complications during and after surgery
5. Details of lengthenings performed and how this is measured
6. Details of revision surgery including rod revision and definitive fusion.

As there is no OPCS code for this procedure, payment will be dependent on and determined by data entry into the BSR including all lengthenings in the outpatient clinic

8. Patient pathway

All spinal units performing this procedure will have already performed it in the past or will have performed surgically lengthened rods.

1. A child who meets the criteria will be consented for non-invasively lengthened spinal rods. Information about the procedure, its aims, risks and follow-up protocol will be given to the parents/guardians.
2. Discussion at Spinal MDT to confirm the need for the procedure and discussion of other options. Spinal levels of surgery to be defined.

3. Surgery with insertion according to manufacturer's recommendations
4. Completion of British Spine Registry (BSR) Form with information defined above
5. Lengthenings every 3 months in outpatients with radiological or ultrasound confirmation of lengthening. Data entered into BSR at each visit
6. A radiograph must be performed at least yearly to confirm there are no implant complications and document amount of lengthening. Data entered into BSR
7. Device exclusion claimed at 1 year with data from BSR
8. All complications and revision surgery collected on BSR and where complications require revision surgery, this should be discussed at the Spinal MDT.
9. Once 4.8 cm lengthening completed, further discussion at Spinal MDT to decide whether to perform a definitive fusion or insert further non-invasively lengthened rods (depends on age and growth potential)
10. Definitive spinal fusion defines the end of the data collection for this device.

9. Governance arrangements

The facilities required to perform this surgery are already carefully defined in the D14 Service Specification. Trusts must be meeting the requirements for paediatric spinal deformity surgery within the specification to be able to perform this procedure and claim the device exclusion payment.

A National Annual report will be produced by the BSR to identify any clinical concerns.

10. Mechanism for funding

Non-invasive lengthening spinal rods will be funded by NHS England dependent on data completion in the British Spine Registry**.** Payment through a device exclusion of £5,000 per rod is recommended. In most cases two rods will be inserted giving an overall device exclusion cost of £10,000.

11. Audit requirements

The intervention will be commissioned with a mandate that centres collect prospective data built into the British Spine Registry to monitor clinical effectiveness and safety (though the contract information schedule). The British Spine Registry will develop a special sub-form to collect this information and all surgeons doing these procedures on the NHS have access to the Registry. A report on these cases will be produced monthly or as often as required at no cost to monitor the implementation, outcomes of this procedure in a similar way as the National Joint Registry does.

12. Documents which have informed this policy

Solutions for Public Health Evidence review on non-invasive lengthening spinal rods for Scoliosis.

13. Links to other policies

Not Applicable.

14. Date of review

This policy will be reviewed in April 2016 unless information is received which indicates that the proposed review date should be brought forward or delayed.

References

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Appendix 1: Ellipse Technologies, Inc. MAGEC™ Spinal Bracing and Distraction System Instructions for Use

Product Description:
The Ellipse Technologies, Inc. **(ETI) MAGEC™ Spinal Bracing and Distraction 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 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 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 implantable 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.

Intended Use:
The implanted 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 External Remote Controller. The rod is implanted and secured using standard fixation devices (pedicle screws, hooks and/or connectors).

Contraindications:
• Infection or Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
• Metal allergies and sensitivities.
• Patient with Pacemaker
• Patient requiring MRI imaging during the expected period device will be implanted
• Patients younger than two years old.
• Patients weighting less than 25 lb. (11.4 kg)
• Patients and/or families unwilling or incapable of following postoperative care instructions.

Warnings
• The ETI MAGEC Bracing and Spinal 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 open.
•. Metallic implants can loosen, fracture, corrode, migrate, or cause pain.

The MAGEC Actuator is supplied sterile and is for single use only. The actuator has not been tested to be cleaned or sterilized for multiple uses. If the actuator is used more than once, the device may not be sterile and could cause a serious infection.

Precautions
• Do not use this device without proper training in both device implantation and adjustment. Refer to External Remote Controller (ERC) Operator's Manual (OM0000) for operation of External Remote Controller.
• Assure that distraction length is assessed by X-ray imaging immediately after non-invasive adjustment procedure, and also at a minimum of once every six months.
• Assure that patient with implanted device does not enter MRI unit. Effect of high magnetic field of MRI unit has not been studied with respect to the implanted magnet and is therefore unknown.
• 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 period of implant, patient should not participle in contact or severe sports such as weightlifting, tumbling, gymnastics, rowing, or other high risk activities.

• During period of implant, patient should limit backpack weight to 20% of body weight or less.
• During period of implant, patient should limit backpack weight to 20 lb. (9 kg) or less.
• Assure 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.
• 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 implant carefully prior to use to assure proper working condition. If you suspect a component to be faulty or damaged, do not use.
• Always place the rod in patient so that the “CEPHALAD” arrow on the actuator points toward head (cephalad) in 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.

Cautions
• This device is for prescription use only by the order of a physician.
• Device should be removed after implantation time of no more than six years.
• Device should be removed if skeletal maturity has been reached.
• Device should be removed after active distraction period has ended.
• Device should be removed or replaced if maximum distraction length of device has been attained, and patient is still in active growth phase.
• Utilize extreme caution when handling instruments made from magnetic materials such as stainless steel in proximity of the magnet of the actuator, as materials will be attracted to each other.
• When cutting rod to desired length, take care not to leave any sharp burrs.
• Do not bend actuator.
• Do not overbend any of the bendable rod portions (multiple times).
• If retraction of device is needed, never retract device more than the amount lengthened the preceding week. 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 (OM0000) to assure proper alignment between ERC and magnet of the actuator.

Detail of System
Each of the components is packaged separately. The rods are available in three diameters, 4.5 mm, 5.5 mm and 6.35 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.

Procedure

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 Ellipse Technologies, Inc. MAGEC Bracing and Spinal system along with the associated instrumentation to facilitate correct selection and placement of the implants.

In addition, follow instructions for use for the standard fixation devices to be used.

Implantation Procedure - Initial

1. Determine desired anchor sites and determine desired foundation constructs for proximal and distal fixation. It is recommended that proximal foundation utilize multiple screws or hooks. For example: claw construct, bilateral construct with cross connector.
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 Ellipse rod. They should not be directly over the rod.
3. Expose spine at each anchor site.
4. Create foundation to spine at each anchor site.
5. Tunnel Ellipse rod subcutaneously between each anchor site.
6. Distract spine as needed and secure Ellipse rod to each anchor site.
7. Close patient per normal procedure.

Implantation Procedure (Revision)

1. Determine desired anchor sites or attachment points (to existing instrumentation) and determine desired foundation constructs for proximal and distal fixation (if applicable). It is recommended that proximal foundation utilize multiple screws or hooks. For example: claw construct, bilateral construct with cross connector.
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 not in line with the expected location of the Ellipse rod.
3. Expose spine at any new anchor site to be used. (if necessary)
4. Create foundation to spine at anchor site(s). (if necessary)
5. Tunnel Ellipse rod subcutaneously between each anchor site.
6. Secure Ellipse rod at each end, either by attachment to foundation or by attachment with pre-existing instrumentation.
7. Distract spine as needed and secure Ellipse rod.
8. Close patient per normal procedure.

Post Operative Procedures

1. Read the External Remote Controller (ERC) Operator's Manual (OM0000) prior to performing an adjustment of the implanted rod using the External Remote Controller.
2. Lie patient prone.
3. Carefully place External Remote Controller over patient per operating instructions, balancing device at base of handles on index fingers.
4. Identify the portion of back in which the implanted magnet is located. Feel magnetic attraction from External Remote Controller to implanted magnet, and place External Remote Controller firmly over this area.
5. Distract the desired amount, as viewed on External Remote Controller display. If there is any discomfort or pain in patient, External Remote Controller can be used to retract implant.
6. Carefully place External Remote Controller back in its storage container and close.
7. Patient should always be x-rayed after adjustment in order to confirm the amount of distraction. Refer to External Remote Controller (ERC) Operator's Manual (OM0000) for sample X-ray image and method of estimating distraction length from distance between magnet and rod.

Implant Removal Procedures

1. At the time deemed appropriate by the physician, the implant and associated accessories will be removed using standard surgical technique.
2. The explanted product will be returned to Ellipse Technologies, Inc. following instructions provided by the Company. Please call the Company +949-837-3600 to obtain instructions or to answer any questions.

Dual Rods

1. It is recommended that at least one cross connector (not supplied by Ellipse) be used between the rods either proximally or distally.
2. 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. 1). This will assure unimpeded access by External Remote Controller (ERC).
3. When using a standard rod together with an offset rod (Fig. 1), it is recommended that a cross connector be used proximally or distally, but not both proximally and distally.
4. In a patient having dual rods consisting of a standard rod and an offset rod, the rods will be lengthened independently (one at a time) with the External Remote Controller (ERC).
5. In a patient having dual rods consisting of two standard rods (or two offset rods), the rods will be lengthened together (at the same time) with the External Remote Controller (ERC).

The Spinal Rod is available in two general configurations, Standard and Offset, which use the same mechanism, but with the magnet at opposite ends of the actuator. On the Standard configuration, the distraction occurs above (proximal) the actuator and on the Offset configuration, the distraction occurs below (distal) the actuator.
Before using rod/actuator, remove the silicone caps on each end and discard.