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# The impact and surgeon perceptions of the suspension of the CE certification of MAGEC devices on clinical practice

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## Abstract

**MAGnetic Expansion Control (MAGEC) rods are used in the surgical treatment of children with early onset scoliosis. The magnetically controlled lengthening mechanism enables rod distractions without the need for repeated invasive surgery. The CE certification of these devices was suspended in March 2021 due, primarily, to performance evidence gaps in the documents provided by the manufacturer to regulators and notified bodies. MAGEC rods are therefore not permitted for use in countries requiring CE marking. This was a survey of 18 MAGEC rod surgeons in the UK about their perception of the impact of the CE suspension on the clinical management of their patients. Unsurprisingly, virtually all perceived a negative impact, reflecting the complexity of this patient group. Reassuringly, these surgeons are highly experienced in alternative treatment methods.**

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## Background to MAGEC devices

The MAGnetic Expansion Control (MAGEC) rod (NuVasive Specialised Orthopaedics (NSO), USA) is a design of magnetically controlled growing rod (MCGR) that has been used in the surgical treatment of children with scoliosis.

The intended use of the rod is to brace the spine while minimizing the progression of scoliosis as the child grows. This design is advantageous over traditional growing rods (TGRs) as lengthening of the rod, in line with growth of the child, is achieved every one to six months with the use of an external magnet in an outpatient clinic setting.[1] This is in contrast to the use of TGRs, which require repeated invasive surgery under general anaesthesia to lengthen the rods. MAGEC rods are routinely removed from the patient after they have been extended to their full length.

## CE certification suspension of MAGEC devices

By law, all medical devices sold in European Union (EU) Member States must have a valid CE certificate. While the UK has left the EU, the UK will continue to recognize and require CE certification for all medical devices placed within its market, until 30 June 2023.[2]

On 25 March 2021, the European Notified Body for NSO temporarily suspended the CE certification of all MAGEC devices, as well as all PRECICE devices, which are used in lower limb treatments and are also magnetically controlled.[3]

The sale of these devices is not permitted in any country requiring a CE mark. NSO have also voluntarily suspended the sale of these devices in countries not requiring a CE mark until the CE certificate is reinstated.

## Why was the CE certification suspended?

On 1 April 2020, NSO voluntarily suspended the supply of all MAGEC rods to the UK while the UK Medicines and Healthcare products Regulatory Agency (MHRA) undertook an investigation into the performance of these devices.[4] This investigation was prompted by several earlier Field Safety Notices (FSNs) and Medical Device Alerts (MDAs) of a risk of failure of the rods, associated with wear and/or corrosion of the titanium components.

The MHRA investigation identified gaps in the technical documentation for these rods, which is required for all medical devices.

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This resulted in an audit of all documentation for NSO's MAGEC and PRECICE devices by the manufacturers' European Notified Body. The audit confirmed that there were evidence gaps in the documentation and took the action of suspending the CE certification until these gaps are addressed. It must be emphasized that this decision was entirely necessary, given that some data required for CE marking were missing, and indeed reflects the se of these omissions.

## Use of MAGEC rods: what do the guidelines say?

The MHRA has stated that surgeons must not implant MAGEC rods in the UK until further notice. While the regulator had previously permitted the use of the rods in exceptional circumstances (during the period in which their use was suspended but the CE mark was still valid), the MHRA will now no longer accept applications from surgeons to use the rods in exceptional circumstances until such time that the CE certification is reinstated.[3] This moratorium on the implantation of these devices even under a humanitarian exemption is uncommon, and reflects the extent of the concerns from the regulator over their use in their current format.

## What is the impact on clinical practice?

We created a survey of nine questions in order to better understand the impact that the suspension of the CE mark of MAGEC devices has had on the clinical management of patients who may otherwise have received one of these devices. The survey was disseminated to all spine surgeons within our surgeon network who had used or were planning to use MAGEC rods in their clinical practice (n = 31). We received responses from 18 surgeons practising in the UK. All responses were anonymized. The following summarizes their responses to the nine questions:

- 89% of surgeons surveyed were routinely implanting MAGEC rods prior to the suspension of the CE mark.
- 100% were intending to implant MAGEC rods prior to their suspension.
- 67% experienced delays in obtaining MHRA approval to use the rods in an exceptional basis prior to the suspension of the CE mark.
- 61% are not aware of the reasons for the CE mark suspension.
- 17% agree with the decision to suspend the CE mark, 39% disagree, and 44% neither agree nor disagree.
- 94% feel the CE mark suspension has had a negative impact on the clinical management of their patients.
- 100% intend to implant MAGEC rods if/when the CE mark is reinstated.
- In the surgical treatment of new patients, 33% intend to wait to see if the CE mark is reinstated and implant a MAGEC rod (if clinically acceptable for the patient to wait), 44% will implant a traditional growing rod, 17% will use an alternative treatment method, and 6% (n = 1) are unsure.
- In the surgical treatment of current patients with MAGEC rods (e.g. those requiring upsizing of their rods), 39% intend to wait to see if the CE mark is reinstated and implant a MAGEC rod (if clinically acceptable for the patient to wait), 50% will implant a traditional growing rod, and 11% are unsure.

## Discussion

The suspension of the CE mark by the manufacturer's notified body was a necessary step due to the gaps in the technical performance documents that are required for a medical device to have this certification, coupled with the previously documented issues with its function. The withdrawal of a medical device in this manner is a rare occurrence, and a clear indicator of the significance of the omissions by the manufacturer. It is appropriate that the rod is not permitted for use in patients until such time that the data gaps are addressed by the manufacturer and the reissuing of the CE mark is considered.

Virtually all surgeons surveyed were routinely implanting MAGEC rods prior to its suspension, and all intend to implant these devices if/when the CE mark is reinstated. While the suspension of these devices is clearly justified, it is not surprising that these surgeons perceive this suspension as having had a negative impact on the clinical management of their patients. We must emphasize that not all surgeons who were invited to respond to this survey (n = 31) did so; the responses presented here therefore may not be representative of all scoliosis surgeons practising in the UK.

The perception of a negative impact may in part be explained by the the apparent variability in how surgeons intend to manage their patients in the absence of MAGEC rods. Approximately half of those surveyed will opt to now implant traditional growing rods, which will require repeated invasive surgery to enable rod lengthening.

One-third of surgeons surveyed will wait where they can for the MAGEC rod CE mark to be reinstated (if at all); there may be a risk of curve deterioration and a potential effect on cardiorespiratory function.

Some surgeons will consider alternative treatment options, and two surgeons were unsure of how they would best approach management. It is important to emphasize that many of the surgeons surveyed run high-volume practices with considerable prior experience in the use of alternative treatment methods, including TGRs; the decision to revert to these options is in the interest of good clinical practice.

Surprisingly, 61% of surgeons (n = 11) were not aware of the precise reasons behind the suspension of the CE

mark and only 17% (n = 3) supported the decision to suspend it. This may highlight a need for regulators and manufacturers to improve the communication of this information to surgeons or, perhaps, that more information needs to be provided to explain the rationale for decisions that are made. Equally, surgeons must always be responsible for staying up to date on research into and outcomes of the devices they use.

More broadly, the responses from surgeons about the use of these devices may also reflect the complexity and difficulty in treating the early onset scoliosis (EOS) patient group, and indeed that there is no perfect solution. Concerns over metallosis have been well documented,[5] however these may also be applicable in the use of TGRs. Alternative treatment methods will present with a different series of challenges, including the risk of infection, rod breakages, and autofusion. It is clear however that if these rods are used, they must be done so with enhanced clinical and radiological follow-up.

In conclusion, the suspension of the CE mark of MAGEC rods was necessary due to gaps in the regulatory data provided by the manufacturer, and the seriousness of these omissions is reflected by this suspension. Our survey of 18 MAGEC rod surgeons showed, unsurprisingly, that they perceived the CE mark suspension as having had a negative impact on their patient management. Reassuringly, however, these surgeons are highly experienced in alternative treatment methods for managing this complex patient group.

## Take home message

- This was a survey of 18 MAGnetic Expansion Control rod surgeons in the UK about their perception of the impact of the CE suspension on the clinical management of their patients. Unsurprisingly, virtually all perceived a negative impact, reflecting the complexity of this patient group.
- Reassuringly, these surgeons are highly experienced in alternative treatment methods.

## Supplementary material

Survey questions and answers.

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