Freedom of Information Act 2000 - Request Reference FoI/21/223
MAGEC Regulations and Correspondence

Request details

1. **We request all correspondence (and attachments between January 1, 2021 and the present) between Cardiff and Vale University Health Board and the Medicines and Healthcare Products Regulatory Agency ("MHRA") regarding health risks relating to the MAGEC System. Magnetically Controlled Growing Rods system ("MAGEC System")**

Cardiff and Vale University Health Board does not hold this information. Under our Section 16 obligation, the duty to provide advice and assistance, I would like to inform you that, the UHB would be able to provide the MHRA Targeted Device Safety Information (TDSI) which was circulated by British Scoliosis Society to all the members. There is no correspondence from the UHB to the MHRA.

2. **All guidance received from MHRA regarding safety risks to patients who have received MAGEC System implants.**

Please see above.

3. **All guidance received from MHRA regarding removal of MAGEC Systems (or components) from patients.**

https://www.nuvasive.com/wp-content/uploads/2021/04/Company-statement_MAGEC-and-Precice-CE-Mark_09April2021.pdf

Targeted communication: CE mark suspended for all MAGEC systems manufactured by NuVasive Specialized Orthopedics, Inc. - GOV.UK (www.gov.uk)

We are in the process of communicating with the patients that:

- Have the device and are currently undergoing treatment.
- Have the device and the device has been left in and not requiring further intervention.
- who had the device in the past (the MAGEC growing rods exchanged for definitive fusion)
- Patients who will come in for growing rods in the future with whom we discuss the above information regarding the risks.