

Ref: PQ 31321/23

Sláinte Leanaí Éireann (SLÉ), Herberton, Siúlán San Séamas, Rialto, D08 HP97, Éire Children's Health Ireland (CHI), Herberton, St James's Walk, Rialto, D08 HP97 Ireland

11th July 2023

Deputy Paul Murphy Dáil Eireann Dublin 2

Dear Deputy Murphy

I refer to your below parliamentary question which has been forwarded to me for attention.

PQ 31321/23: To ask the Minister for Health if he will outline the complications, if any, that have been associated with the use of magec rods in Crumlin Hospital, specifically related to end cap separation as well as metalosis.

Children's Health Ireland (CHI) Response:

Magec is still the recommended implant for certain cases of early onset scoliosis internationally, and in Children's Health Ireland (CHI) at Crumlin we apply to the Health Products Regulatory Authority (HPRA) to sanction the use of Magec rods on a case by case basis.

CHI at Crumlin currently have 21 patients with MAGEC in-situ. Clinical advice is that titanium and cobalt blood serum tests are offered to the majority of children with Magnetic Controlled Growth Rods (MCGR) implanted and samples are taken prior to the scheduled removal of rods and final deformity treatment (that is typically a final correction and fusion).

Metallosis is a descriptive finding, it is not always associated with adverse outcomes, clinical relevance or any negative impact. The clinical relevance of metallosis is under continued discussion and review. There are no standardised tests for levels and no recommended ranges. It is a research investigation, not a clinical tool at present. There is no information a test will provide that can be reasonably acted on. The decision to offer these tests is made by each Consultant Orthopaedic Surgeon.

The Health Products Regulatory Authority (HPRA), has advised that any requests for information relating to their investigation should be sent directly to the HPRA at <u>PQsandBriefings@hpra.ie</u>

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Yours sincerely

HAR

Dr. Ike Okafor Clinical Director Email: <u>Ikechukwu.okafor@nchg.ie</u>

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