Children's Health Ireland

Crumlin | Temple Street | Tallaght | Connolly

MANAGEMENT OF EXPLANTED MAGEC RODS IN THEATRE

Area of use:	All of organisation ☐	CHI at Connolly ☒	CHI at Crumlin ☐
	CHI at Herberton ☐	CHI at Tallaght ☐	CHI at Temple Street ☐
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1.0 Introduction

MAGEC growing rods are part of the MAGEC™ (MAGnetic Expansion Control) System, a surgical treatment for children with severe spinal deformities. The system includes implantable rods and an external remote control, used to brace the spine while the child is still growing to minimise the progression of scoliosis.

Magec rods explanted in CHI at Crumlin Hospital are currently included in a research study at, The London Implant Retrieval Centre (LIRC), for Biomedical Engineering, Royal, and National Orthopaedic Hospital (RNOH) Stanmore London HA74LP. The lead for the study is Dr. Hari Hothi and the collaborating Consultant Orthopaedic surgeons at CHI Crumlin are Mr. Jaque Noel and Mr. Patrick Kiely.

The explanted Magec rods are classified as unclean medical devices and transport to another facility must be incompliance with The European Agreement Concerning the International Carriage of Dangerous Goods by Road 2015 (ADR) and the Health and Safety Authority Competent Authority Exemption 03/2016 (expiry date 30th June 2018) HSE Ref QPSD-GL-021-1

This policy outlines the procedure to follow in CHI at Crumlin Hospital when Magec rods are explanted from patients in theatre.

2.0 Applicable to

All theatre staff

3.0 Objectives of Standard Operating Procedure

To provide specific guidance to staff on the process

4.0 Procedure in Theatre

- Explanted rods that are not included in the research study at the London Implant Retrieval Centre (LIRC), for Biomedical Engineering, Royal, National Orthopaedic Hospital (RNOH) Stanmore London HA74LP must be disposed of safely in compliance with normal CHI waste management protocol and must not be given to patients even if requested unless written approval is given by the hospital's Chief Executive Officer.
- In compliance with the Implant Study LIRC the explanted rods **must not** be sent to HSSD for decontamination
- When a Magec Rod is removed from the patient, the scrub nurse is responsible to wipe it down with a saline swab, remove all visible body fluid and tissue and dry it with a clean dry swab.
- The scrub nurse hands off the implant to the circulating nurse.
- The circulating nurse wraps the implant in the fluid absorbing towel that comes with the biohazard bag, then seal the implant into the biohazard bag ensuring excess air is expelled
- The inner packaging is placed in a biohazard plastic bag, and tied securely with a swan-neck style closure using a cable tie as per figure 1.

- The explanted implant is then placed into the specific cardboard box supplied.
- A patient addressograph label must be attached to the inside lid of the cardboard box dated and signed by the circulating nurse. The addressograph label **must not be** attached to either of the biohazard bags.
- The box must be sealed with adhesive tape.
- The specific absorbent towels, biohazard bags and cardboard boxes for the study are stored in Theatre 8 storeroom. All these items are supplied to the department by the LIRC.
- It is the responsibility of the CNM2 in the spinal theatre 8 to ensure adequate supply of the above is available.
- The nurse is then responsible to lock the box containing the explanted rod into the top drawer of the first filing cabinet in the CNM III Office (labelled Magec Rods) and document the details of this in the logbook within titled "Magec Rod log book".
- The cabinet must be maintained locked at all times.
- The responsibility for the security and management of the key sits with the CNM2 in Theatre 8.

5.0 Magec Rods from CHI patients explanted in other Health Care organisations

Some spinal services are outsourced to other healthcare organisations from CHI at Crumlin. As a result, some patients who had their original spinal fusion conducted at CHI Crumlin may have their rods explanted in another hospital, either a private hospital or other CHI hospital.

Appendix 1 is an instruction sheet to guide the perioperative nursing and medical staff as to how to handle, package and transport the contaminated medical device to be transported to Orthopaedic Theatre Clinical Nurse Manager at CHI Crumlin. When received in Crumlin the explanted device will be transported to the research study at, The London Implant Retrieval Centre (LIRC), for Biomedical Engineering, Royal, and National Orthopaedic Hospital (RNOH) Stanmore London HA74LP.

6.0 Procedure for preparation and Transport of explanted Magec Rods to the LIRC London

- Due to costs associated with shipping, explanted implants will not be dispatched to the LIRC until there is a minimum of four or more rods ready for transport.
- All packaging and shipping costs are the responsibility of the research centre at the RNOH, including liability insurance.
- It is the responsibility of the Orthopaedic SpR at CHI Crumlin to contact Dr. Hari Hothi / or Dr. Mala Mascarenhas at London Implant Retrieval Centre, Royal National Orthopaedic Hospital, Brockley Hill, Stanmore, London. HA7 4LP
- Emails: hari.hothi@nhs.net Tel + 0044 7525 432 132 or mala.mascarenhas@nhs.net + 0044 208 420 6328 to arrange transport and payment.

7.0 Preparation for Transport

Before the implants are transported to the research centre at LIRC, the following criteria must be met:

- Consent for research participation obtained from patient's parents / the nurse preparing the explanted rods for transport must verify guardians.
- It is the responsibility of the Orthopaedic consultant at CHI Crumlin to obtain consent. (Consent forms are available in Theatre 8 and the Orthopaedic Office, Level 4 Nurses Home).
- An Orthopaedic specialist registrar(SpR) is assigned by the department
- Consultant Orthopaedic lead to safely manage the process of preparation, transport and associated documentation for explanted rods sent to the research centre.
- The assigned SpR is responsible to maintain and update the excel database at CHI Crumlin of explanted Magec rods sent to the LIRC.
- Access to this database is limited to CNM III Theatre and Orthopaedic Medical team.
- The assigned SpR will create a unique identifying number (UIN) for each patient, and print on an adhesive label.
- The criteria for generating the UIN is as follows: The patient initials are combined with next number in order on the excel document, e.g. patient Joe Blogs explanted rod number 17 = UIN: JB17
- The SpR in collaboration with the CNM2 in theatre 8 will remove the explanted rod from the cardboard box and adhere the UNI to the plastic biohazard bag.
- The packaged rods for dispatch must then be sealed into an impenetrable outer box specifically supplied for purpose, which meets with UN approved packaging UN4H2 approved boxes. HSE Ref QPSD-GL-021-1 **Figure 2**
- The transport box must be maintained to a standard that will maintain UN approval, i.e. the condition at the time of purchase.
- All spaces in the box must be packed and used to prevent movement of devices within the box

Figure 2

- The shipping box can be obtained from the Orthopaedic Office, Level 4 in the Nursing Home Building
- It is the responsibility of the SpR to ensure a supply of the above boxes are available when required

Contact for Supplier for Transportation Box:
O'Leary Medical
Howth Junction Business Centre,
Kilbarrack, D05 AX70
Company Rep: Ryan
Tel: 086 465 0270

Shipping Company: Federal Express. Tel: 01 866 9290

- No other patient identifiers are to be included / attached with the implants when transported to the research centre, only the UIN
- When required, Orthopaedic Registrar assigned to the study will bring the outer box to Theatre. Once loaded with the implants, the outer box will be labelled with the address for the LIRC care of DR Harry Hothi and secured with six cable ties.
- It is the responsibility of the Orthopaedic SpR to document / record the list of patient rods transported to the LIRC on the excel database.
- The SpR will arrange the collection time with the Shipping Company and confirm details with the CNM 2 in theatre 8 to ensure the implants are ready when transport arrives to collect them.
- The explant implant can only be collected from the theatre department.
- CNM is responsible to record that the implant has been picked up in the log Book (Explanted Magec Rod log book)
- The exterior of the shipping box is marked "USED MEDICAL DEVICE" or "USED MEDICAL EQUIPMENT".
- Any incident in loss of content of a substance during the transport journey shall be reported immediately to the Health and Safety Authority (HSA).

8.0 Implementation Plan

Education with regard to the above process will be prepared and delivered by CNM 2 and CNM 1 Theatre 8 and Clinical Nurse Facilitator for the spinal theatre to the relevant Nursing / Medical Staff.

A copy of this protocol will be placed in the SOP folders, in OT 8, the hospitals online policy folder and the Orthopaedic office, level four of the nursing home. It is the responsibility of both CNM 2'sin the Orthopaedic theatres to ensure this protocol is implemented as written.

A review of the efficacy of the process will be carried out after each new batch of rods are dispatched in collaboration with the assigned SpR and the CNM 2 theatre 8. Amendments to the protocol will be made if required in collaboration with the Unit CNM 3

9.0 Evaluation and Audit

Audit of the above process will be observed independently by the Department Quality Facilitator for three rods each time a group are being dispatched from the hospital when they are prepared and transported to the LIRC for study. Results will be reported to the Theatre Managers CNM 3's and The Management Committee.

It is the responsibility of the CNM's in theatre 8 to ensure that the quality facilitator is informed when rods are being prepared and dispatched to the LIRC.

10.0 References

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Appendix 1 - Instruction for preparation, packaging and transport of explanted Magec Rods

Instruction for preparation, packaging and transport of explanted Magec Rods of CHI patients from other Health Care Organisations in Ireland to CHI at Crumlin Hospital

This procedure does not apply to non-CHI patients

The Consultant Surgeon who is explanting the Magec rod in the other hospital is responsible to collect the blue container from the CNM T8 in CHI at Crumlin. The CNM is responsible to ensure the box contains the following:

- Instruction Sheet
- Absorbent Towels
- Biohazard Plastic Bags x 3 (suitable size to contain the implant safely)
- Cable ties by 2
- In compliance with the Implant Study LIRC the explanted rods **must not** be sent to HSSD for decontamination
- When the Magec Rod is removed from the patient, the scrub nurse is responsible to;
- Wipe it down with a saline swab, remove all visible body fluid and tissue and dry it with a clean dry swab.
- The scrub nurse hands off the implant to the circulating nurse.
- The circulating nurse wraps the implant in the fluid absorbing towel that comes with the biohazard bag and places the implant into the biohazard bag ensuring excess air is expelled
- Then place it into a second biohazard bag ensuring excess air is expelled also.
- The two bags must be tied and secured with a swan-neck style closure using a cable tie as per figure 1.

- To support safe handling of the rod when received back at Crumlin it must be put into a 3rd plastic biohazard bag and a second swan neck cable tie applied to the third bag only.
- Attach the patient's addressograph **to the third bag** only. (NB; it is important not to attach the addressograph to the second bag)
- The explanted implant is then placed into the blue contained and the lid is attached securely
    - **Do not adhere patient addressographs to the blue container**
- Ensure the outside of the blue container is labelled for the urgent attention of;
- Orthopaedic Spinal Theatre CNM, CHI at Crumlin Hospital
- When the implant is safely packed the perioperative circulating nurse is responsible to ensure it is given to the
- Consultant Orthopaedic Surgeon who conducted the operation to take back to Crumlin hospital.

- The Consultant Surgeon is responsible to ensure the explanted rod is handed to the spinal theatre CNM at CHI Crumlin as soon as possible.
- The Crumlin CNM will document receipt of the rod when received in the explanted rod logbook
- *The third bag with the patient's detail is removed in Crumlin when the implant is transferred to London*