University Hospitals of Leicester NHS
NHS Trust

Policy for the management of patients undergoing podiatric surgery within the Alliance using Stimulan Rapid Cure® Device.

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CONTENTS

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

Not applicable- Version1

KEY WORDS

Stimulan Rapid Cure®, Gentamicin, Vancomycin, Podiatric Surgeon

1 INTRODUCTION AND OVERVIEW

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trust Policy and Procedures for the Alliance for the management of patients undergoing podiatric sugery requiring the use of an antibiotic impregnated medical device (Stimulan Rapid Cure®) where there is underlying infection resistant to and not responding to standard treatments.

1.2 Stimulan Rapid Cure® - SRC is a calcium compound device used to regenerate and repair bone and soft tissue. Used as a bone graft substitute containing calcium matrix powder which when mixed with mixing solution (and/or antibiotics) creates a resultant paste. This resultant paste when placed into the bead mat sets to form appropriately sized beads. The biodegradable, radiopaque beads are packed into open voids/gaps and resorbed in approximately 30-60 days.

1.3 As a bone graft substitute, SRC is classed as a Medical Devices and governed by the MHRA under the following regulations:

- the Medical Devices Regulations 2002 (SI 2002 No 618, as amended)
- the General Product Safety Regulations 2005 (SI 2005 No 1803)

1.4 This medical device (SRC) is intended for use as a bone void filler for voids or gaps, and when used a bone graft substitute resorbs and is replaced with bone during the healing process. The concurrent use of antibiotics (for use with infected wounds) is an additional advantage that can provide local action for resistant wounds/ bone malformations due to recurrent underlying infections however has not been assessed by a European medicines competent authority and is therefore considered off-label usage of this medicinal product. The antibiotics added to the matrix are licensed products and will be limited to gentamicin and vancomycin.

1.5 Patients are reviewed in the UHL diabetes foot clinic with the Podiatric Surgeon and then due to requirements will be referred for assessment and management to the Podiatric Surgeon within the Alliance for further treatment using the above products.

2 POLICY SCOPE –WHO THE POLICY APPLIES TO AND ANY SPECIFIC EXCLUSIONS

2.1 This policy applies to:

- Podatrists
- Podiatric Surgeons
- Medical staff involved with referral to podiatric surgery (Multidisciplinary Team within Diabetes)

3 DEFINITIONS AND ABBREVIATIONS

3.1 Calcium compound medical devices (specifically Stimulan Rapid Cure®)

Calcium compound devices range from bone graft substitutes to bone matrices and can be used to regenerate and repair bone and soft tissue. They are intended for use as bone void filler for voids or gaps that are not intrinsic to the stability of the bone structure. These specific compunds are calcium sulphate designed for use in infection or dead space management. They can be inserted directly at the site of infection in bone voids or defects.

3.2 Podiatric Surgery

Podiatric surgery is a specialist field in the podiatry profession. Podiatric surgery is the surgical treatment of conditions affecting the foot, ankle and related lower extremity structures by accredited and qualified specialist podiatrist

3.3 Podiatric Surgeon

Podiatric Surgeons are podiatrists who have had extensive postgraduate training in the surgical management of foot and ankle problems.

3.4 Locally administered antibiotics (and antifungals)

For the purposes of this policy, locally administered antibiotics, is referring to in the main, the addition of gentamicin injection and vancomycin powder for injection licensed products, mixed with the sterile calcium compound matrix powder. Other antibiotics and antifungals can be prescribed where it is felt necessary by the Multi Disciplinary Diabetes Foot Team.

3.5 Patient Specific Direction (PSD).

A **Patient Specific Direction** (PSD) is a written instruction, signed by a prescriber for medicines to be supplied and/or administered to a named **patient** after the prescriber has assessed the **patient** on an individual basis.

3.6 Multi-Disciplinary Diabetes Foot Care Team (MDFT).

The Multi-Discplinary Foot Care team led by a named healthcare professional, and consisting of specialists with specific skills (including and not exclusive to Diabetology, Podiatry, Microbiology, Vascular Surgery etc) that review all patients with acute foot problems.in line with the care pathway in accordance with NICE guidance.

https://www.nice.org.uk/guidance/ng19/chapter/Recommendations#diabetic-foot-ulcer

4 ROLES – WHO DOES WHAT

4.1 The Board Lead responsible for this policy is the Medical Director

4.2 Chief Pharmacist

The Chief Pharmacist is responsible for:

4.2.1 The safe management and prescribing of drugs within the Trust and the UHL pillar of the Alliance

4.3 Clinical Management Group (CMG)

4.3.1 The Clinical Director and Head of Nursing Quality and Safety for the UHL Alliance Clinical Management Group (CMG) are responsible for ensuring staff in their area are aware of this policy.

4.3.2 The Clinical Director and Head of Nursing for the Diabetes Foot Clinic are responsible for ensuring staff in their area are aware of this policy.

4.4. Podatric Surgeon

4.4.1 The podiatric surgeon is responsible for ensuring this policy is adhered to and the guidance is kept up to date and staff working in the Alliance are aware of its contents.

4.4.2 Consultant Diabetes Specialist/DiabetesTeam – support multidisciplinary review of this patient group and determine that standard treatments (extended courses

of both intravenous and oral antibiotics selected according to cultures) have failed to completely treat the patient. The MDFT will make the decision to treat based on clinical presentation. There will be instances where specific patients are recommended surgery as the initial option e.g. marked bone destruction

4.4.3 Ward / departmental staff at Alliance Site (Melton)– stock provision,

Order sufficient supplies of all agents administer according to medicine code and relevant paperwork to cover.

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5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS –WHAT TO DO AND HOW TO DO IT

5.1 Diabetes Foot Clinic

5.1.1Patient is reviewed in Multidisciplinary Diabetes Foot Team (MDFT) clinic.

If patient fits the following criteria:-

- Failure to resolve osteomyelitis
- Further deterioration of the wound
- Adequate blood supply is identified in the affected area
- Patient agrees to the surgery

and standard treatments have not been effective, a decision to treat with antibiotic impregnated calcium compounds is made within the MDFT and a referral is made by the consultant diabetes specialist to the podiatric surgery service to explore podiatric surgery on the affected area and the patient is then referred to podiatric surgery for a procedure.

5.1.2 A Patient Specific Direction (PSD) (Appendix 1) is completed for the patient in the clinic . A copy of the PSD is signed and approved and filed appropriately in the notes. A copy of the PSD is sent through to the appropriate Alliance location in the post or scanned

5.2 UHL Alliance Day Case Units (Melton, Hinckley and Loughborough)

5.2.1 PSD reviewed by Podiatric Surgeon for specific patient on the list and antibiotics selected as appropriate from stock. Drug chart completed for stock control and Alliance medication record completed for patients notes.

5.2.2 .Antibiotic impregnated calcium compound is made up following the full Procedure for making final product according to Stimulan documentation and in accordance with the PSD instructions;

Stimulan Rapid Cure® is checked for expiration date, signs of tampering or damage and sterility. Where instructed, Vancomycin and Gentamicin are checked for expiry date, product and dose with theatre staff. Stickers from Stimulan are placed in the theatre register and patients notes. Outer packaging of Stimulan is opened using an aseptic 'non touch' technique. Stimulan beads are prepared in a sterile theatre environment at the beginning of the procedure as per the following mixing instructions:

- Empty vancomycin 500 mg -1gram powder and the Stimulan Rapid Cure® powder into the sterile mixing bowl provided and mix.
- Add 2 ml of gentamicin liquid (80mg) to the pre-mixed powders and mix thoroughly for 30 seconds until a smooth paste is formed . DO NOT use the mixing solution provided.
- DO NOT over mix. Stimulan Rapid Cure® has a working time of 1-2 minutes and will set approximately 4 minutes after mixing.
- Select the size of bead required and apply a uniform layer of paste onto the bead mat provided. Use the paste applicator to ensure complete filling of each bead cavity.
- Allow the paste to set undisturbed for at least 8 minutes after mixing. Flex the bead mat to release the beads.
- Before implanting the beads, it is recommended that the structural integrity is checked by compressing the bead between thumb and index finger.
- Concurrent use of locally administered antibiotics may affect the setting time, absorption characterisics and / or bone formation.
- The site should not be irrigated following implantation of beads.

5.2.3 Post procedure –

Copy of PSD filed in patients notes and/or filed on the system

Follow-up appointment is made for patient with the Foot Clinic.

Counselling advice - The patient should be advised to report related pain, swelling, fever or unusual incidences. The patient is advised regarding the importance of rest and elevation of the limb. Patient is made aware of surgical risks and possible adverse effects as per consent form .Patient is also informed that this procedure involved using an medication "off-licence" and should be issued with an Unlicensed Medicines Leaflet available from the following link:

http://yourhealth.leicestershospitals.nhs.uk/library/csi/pharmacy/1011-unlicensed-medicines

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 The prescribing & administration of medication is covered in core competencies. Staff should familiarise themselves with relevant policies relating to this.

7 PROCESS FOR MONITORING COMPLIANCE

POLICY MONITORING TABLE

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements Who or what committee will the completed report go to.
Incidents involving Stimulan products and antibiotics Incidents involving podiatric surgery	Medication Safety Pharmacist	Datix	Monthly	Medicines Optimisation Committee (MedOC)

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

- Stimulan® Product Information
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended)
- General Product Safety Regulations 2005 (SI 2005 No 1803)

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 This policy will be uploaded onto the UHL Policies and Guidelines Library accessible by staff via InSite. It will be stored and archived using this system.

10.2 This policy will be reviewed every 3 years or sooner in response to any clinical or risk issues

Appendix 1: Patient Specific Direction

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Patient Specific Direction for the administration of Stimulan® absorbable calcium sulphate beads mixed with chosen antibiotics for the insertion into a diabetic wound

Patient addressograph:

The above named patient is to be referred to the podatric surgery service to undergo podiatric surgery on the named limb (…*left foot*……).

The patient is prescribed …*Gentamicin**… and/or ……*Vancomycin** which when mixed with Stimulan® absorbable calcium sulphate beads is used for insertion in the named limb above. *delete as appropriate

Please tick appropriate box (es)

Drug (s):	**Gentamicin 80mg in 2ml ampoules**	☐
	Vancomycin 500mg-1g Powder for injection	☐
Dose:	**Gentamicin 80mg stat dose** **Vancomycin 500mg -1g stat dose**	

Other alternative drugs: ……☐……

Direction for administration: Mix the above quantity of the selected antibiotic (s) with the absorbable calcium sulphate beads in accordance with the product literature and then insert in the affected limb as per routine procedure.

Signature:……..**Print Name**:……**Date**……
(Authorised Prescriber)

As referring clinician for the named patient, I authorise the following healthcare professional to administer the antibiotic(s), listed above against this patient specific direction, and acknowledge they are competent, qualified and have the necessary knowledge and experience to operate within this direction.

Signature:……..**Print Name**:……**Date**……
(Doctor - Authorised Prescriber)

Name:…*could be pre-printed for Mr Rajesh Jogia*……..
Qualification:
Signature Date