<table>
<thead>
<tr>
<th>NAME OF DOCUMENT</th>
<th>Implantable Intrathecal Drug Delivery System</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYPE OF DOCUMENT</td>
<td>Procedure</td>
</tr>
<tr>
<td>DOCUMENT NUMBER</td>
<td>SESLHDPR/294</td>
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<tr>
<td>DATE OF PUBLICATION</td>
<td>December 2016</td>
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<td>RISK RATING</td>
<td>High</td>
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<td>LEVEL OF EVIDENCE</td>
<td>NSQHS – 4 Medication Safety</td>
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<td>REVIEW DATE</td>
<td>December 2018</td>
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<tr>
<td>FORMER REFERENCE(S)</td>
<td>SESIAHS policy August 2010 - Implantable Intrathecal Drug Delivery System</td>
</tr>
<tr>
<td>EXECUTIVE SPONSOR</td>
<td>Dr Greg Keogh</td>
</tr>
<tr>
<td>EXECUTIVE CLINICAL SPONSOR</td>
<td>Area Clinical Stream Director of Surgery, Perioperative and Anaesthetics</td>
</tr>
<tr>
<td>AUTHOR</td>
<td>Bernadette Bugeja CNC Pain Management POWH</td>
</tr>
<tr>
<td>AUTHORE MAIL</td>
<td><a href="mailto:Bernadette.Bugeja@health.nsw.gov.au">Bernadette.Bugeja@health.nsw.gov.au</a></td>
</tr>
<tr>
<td>POSITION RESPONSIBLE FOR THE DOCUMENT</td>
<td>Bernadette Bugeja CNC Pain Management POWH</td>
</tr>
<tr>
<td>KEY TERMS</td>
<td>Intrathecal, Medtronic SynchroMed® II Pump, IsoMed ® Pump</td>
</tr>
<tr>
<td>SUMMARY</td>
<td>This procedure refers to direct intrathecal drug delivery via an implantable system, for chronic pain relief management and severe chronic spasticity of spinal cord origin.</td>
</tr>
</tbody>
</table>
1. POLICY STATEMENT
This policy relates to intrathecal drug delivery via an implantable system and may be performed on an inpatient or outpatient. This system is used for management of chronic pain and management of severe chronic spasticity of spinal cord origin.

The policy addresses:
  a. the procedure for safe refilling of the implanted system
  b. the safety precautions in relation to undergoing Magnetic Resonance Imaging (MRI).

2. DEFINITIONS
Implantable drug delivery is a system consisting of an infusion pump in a titanium shell (which includes two access ports) and a spinal catheter. The reservoir fill port is used for medication refill. The catheter access port is used for direct access to the intrathecal space for diagnostic purposes. Medications must not be injected via this port. The pump is generally implanted subcutaneously in the left or right abdominal wall.

Medtronic SynchroMed® II Pump – an implantable, programmable, battery powered device that stores and delivers medications intrathecally according to instructions received from the programmer.

IsoMed® Pump – A gas-filled chamber provides a constant flow rate within the pump which exerts a constant pressure on the drug reservoir. This pushes a predetermined volume of medication through the catheter into the intrathecal space. The dose of medication can be changed by altering the medication concentration within the pump.

Tesla - is the unit of magnetic-field strength or magnetic-flux density, commonly denoted as T.

3. RESPONSIBILITIES
- Medical Officers (MO)
- Registered Nurses (RN)

4. PROCEDURE
4.1 Indications for refilling an intrathecal pump
  - Reservoir volume is low or the pump is empty
  - Prescription required for adequate analgesia has changed
  - Medication has changed
  - The length of time between each refill depends on drug concentration, drug stability, pump reservoir volume, daily dose, and various treatment considerations.

4.2 Medications used
Number of drugs can be used alone or in combination. Any intrathecal medications administered must be free of preservatives.
  - Opioids
    - Morphine
    - HYDROmorphine
    - Fentanyl
    - Methadone
• **Local anaesthetics**
  - Bupivacaine
  - Ropivacaine

• **Adjuvants**
  - Clonidine

• **Antispasmodics**
  - Baclofen

The patients must pick-up medications from pharmacy and keep the medications until the refill procedure commences.

4.3 **Prescribing**
Intrathecal pump refill must be prescribed on the Intrathecal prescription and pump refill record (excluding cytotoxic medications), in accordance with [NSW Health PD2013_043 Medication Handling in New South Wales Public Hospitals](#).

4.4 **Equipment Required**
- Medtronic refill kit (includes two non-coring 22G needles, extension tubing with clamp, filter and template)
- Use 10mL and 5mL Leur-lock syringes for IsoMed pump - depending on volume of pump
- Use 20mL Leur-lock syringes for Medtronic SynchroMed® II pump - depending on volume of pump
- Antiseptic to swab skin such as 1% chlorhexidine gluconate in 75% ethanol (BD Persist Plus)
- Dressing pack
- Drawing up needle
- Three-way tap
- Fenestrated towel
- 21G needle (if clonidine or methadone required)
- Sterile gloves
- Intrathecal medications as ordered by the MO (which the patient must keep with them until given to the RN immediately before procedure), or as per hospital site specific protocol
- Sodium chloride 0.9% ampoules if required
- If local anaesthetic required for local infiltration add 2mL syringe, drawing up needle, 25G needle, lidocaine (lignocaine) 2% in 2mL
- Adhesive dressing, e.g. BandAid ®
- Neutral detergent for cleaning trolley eg, Rediwipe Detergent ®
- Sharps disposal bin for immediate disposal at the point of care
- Clinician programmer for the computerised pumps
- Non-sterile template to locate refill access port in SynchroMed® II pump.
4.5 Refill Precautions
- Refill procedure must be performed by trained MO or RN who has been assessed as competent in the refill procedure. In the absence of MO, the more experienced RN will access the pump and second RN will witness and assist.
- Patient’s medical record must be checked for specifications of the pump, i.e. pump model, flow rate and reservoir size.
- Injection of the medication during the refill procedure must be done only through the centre reservoir fill port.
- The timing of refill intervals must be carefully calculated to prevent depletion of drug reservoir and drug withdrawal.
- Strict aseptic technique to be maintained at all times.

4.6 Refill Procedure
- MO or RN does the procedure with another MO or RN as a witness.
- Prepare patient in accordance with Level 2 pre-procedure requirements as per NSW Health PD2014_036 - Clinical Procedure Safety.
- The 5 Moments of Hand Hygiene must be observed throughout the procedure.
- Perform telemetry/interrogate the pump to check current pump status and determine the volume remaining in the reservoir.
- Palpate the pump area to confirm the general pump location and catheter access port orientation. For SynchroMed® II pump use the clean, non-sterile template to outline the pump’s position.
- Check medication with second RN or MO against prescription.
- Open dressing pack, adding equipment required for refill procedure.
- Person attending the refill to perform procedural hand wash using antiseptic liquid soap and water prior to donning sterile gloves.
- Swab pump site with skin disinfectant, 15cm area using a circular motion. Do not go over the same area twice with the same swab.
- Allow at least 20 seconds for skin to completely dry naturally.
- Assemble the needle, extension tubing, three-way tap and empty 10ml syringe.
- Draw up required medications into appropriate syringe size. Attach the 0.22 micron filter to the syringe and prime the filter with the prescribed medication.
- Confirm that the volume of the prescribed fluid does not exceed the reservoir capacity of the pump.
- Place sterile fenestrated towel over the patient, exposing the pump site.
- Place and centre the sterile template over the marked area. Confirm pump’s position by palpating around the pump area and aligning the edges of the template with the edges of the pump. Locate the refill port septum at the centre of the template.
- Insert needle through the centre of the refill port until the needle touches the needle stop. This metal needle stop will damage the needle tip if excessive force is used. Be certain the centre reservoir fill port is being accessed and not the side catheter access port.
- For SynchroMed® II pumps use gentle negative pressure to withdraw the fluid from the reservoir and empty completely eg, until bubbles are present in the extension tubing. For IsoMed pumps the pressurised backflow will automatically empty the residual volume, wait approximately five seconds to ensure all fluid is removed and the pump is empty.
The amount withdrawn should approximately equal the reservoir volume on the pump status screen (SynchroMed® II) or the calculated residual dose (IsoMed) + 25% of the expected reservoir volume. Failure to withdraw all residual solution from the pump may lead to overpressurisation of the pump reservoir.

- If there is no or minimal fluid withdrawn eg, < 1mL, the placement of the needle must be checked by injecting 10 mL sodium chloride 0.9%. Withdrawing back the same amount confirms the needle is placed in the pump’s reservoir.
- Close the clamp and remove the syringe used to obtain residual pump medication. Discard the withdrawn medication.
- The witnessing clinician must record the amount of medication withdrawn on approved hospital medication chart.
- **Note:** if decreasing concentration or changing medications, rinse the reservoir twice with 10mL sodium chloride 0.9% using the refill and emptying procedures described.
- Attach the syringe with the prescribed medication and filter to the extension tubing set.
- Open the clamp and slowly (no faster than 1mL/3 seconds) inject the fluid into the reservoir. Do not force the injection.
- When filling is complete close the tubing clamp and carefully remove the needle from the pump.
- Remove the template and apply firm pressure to injection site for a few seconds with a gauze pad.
- Remove excessive cleansing agent from the skin and apply adhesive dressing.
- Keep gloves on and dispose of all sharps into sharps bin. Remove gloves and repeat hand hygiene.
- For SynchroMed® II pumps program the appropriate new parameters and perform telemetry to update the pump.
- **Note:** if changing concentration or changing medications program, prescription should include a Bridge Bolus.
- Print out the updated patient session and attach to the patient’s medical record.
- Document all appropriate information in patient’s medical record.

### 4.7 Post-procedure Care
- Give the patient written handout reminding them to stay in the clinic area for 30 minutes following procedure, in order to detect any adverse effects of the pump refill.
- Ensure the next refill appointment is booked about one week prior to expected pump empty date. This may vary.

### 4.8 Investigation of Pump Function
- Investigation of the delivery system function is performed in Radiology Department using iodinated contrast.
- Patients with an allergy or contraindication to the contrast may be assessed utilising radiotracer imaging in Nuclear Medicine.
- To determine if the aspirated fluid is cerebral spinal fluid (CSF), it can be tested for presence of glucose, by using a urine test strip. If reading at 30 seconds is positive for glucose eg, trace (5.5mmol/L) or more, the aspirate is positive for CSF.
4.9 Patients with intrathecal pump requiring MRI

- Patients booked for a MRI require the details of the type of implant, manufacturer, make, model and serial number for compatibility check before a booking is made. These will include SynchroMed® II models, 8637-20 (20mL) or 8637-40 (40mL), as well as the IsoMed model: 8472-35-05 35mL @ 0.5mL/day or, 8472-60-10 IsoMed @ 1.0mL/day
- The IsoMed delivery device has demonstrated no impact on pump performance.
- Refer to checklist in Appendix 1 for patients with SynchroMed® II pump.

Management of Patient with Medtronic SynchroMed® II pump

- Programmable pump performance has not been established for greater than 1.5 Tesla horizontal, closed-bore MRI scanners. Patients should not have MRI using greater than 1.5 Tesla horizontal, closed-bore scanners
- Prior to MRI, the physician should ensure the pump is not oriented 90° with respect to the z axis of the MRI scanner (see Appendix 2)
- The magnetic field of the MRI scanner will temporarily stop the rotor of the pump motor and suspend drug infusion for the duration of the MRI exposure. The pump should resume normal operation upon termination of MRI exposure; however, there is the potential for an extended delay in pump recovery after exiting the MRI magnetic field
- While extended delays in pump recovery are unlikely, reports have indicated that there is the potential for a two to 24 hour delay in return to proper drug infusion after completion of an MRI scan
- Medtronic does not recommend programming the SynchroMed® II pump to "stopped pump mode" prior to an MRI because of the possibility of an increased delay in the detection of an extended motor stall
- The SynchroMed® II pump detects motor stall and motor stall recovery. These events are recorded in the pump event log and can be reviewed using the clinician programmer. A motor stall will also cause the pump alarm to sound (two tone alarm). Note: in some cases, the SynchroMed® II pump event log may not register motor stall recovery until after the pump has been interrogated a second time due to the effect of Electromagnetic Interference (EMI) on the pump
- Prior to MRI, the referring MO should determine if the patient can safely be deprived of drug delivery. If the patient cannot be safely deprived of drug delivery, alternative delivery methods for the drug can be utilised during the time required for the MRI scan. If any health concerns arise during MRI procedure then the MRI staff will activate escalation procedure as per hospital policy.

Post MRI interrogation instructions

- Upon completion of the MRI scan, or shortly thereafter, clinicians must confirm that therapy has properly resumed by interrogating the pump with the clinician programmer. For pumps programmed to deliver at least 0.048mL/day, detection of the motor stall should occur within 20 minutes of MRI exposure. Detection of the motor stall recovery and recording of the recovery in the pump event log will typically occur within 20 minutes of the removal of the pump from the magnetic field of the MRI
- Note: both the detection of the motor stall and detection of the motor stall recovery may each take up to 90 minutes if the pump is programmed to minimum rate mode (0.006mL/day). In the unlikely event that electromagnetic interference from the MRI...
scan causes a change to “safe state”, the pump will automatically switch to minimum rate mode (infusion at 0.006mL/day). The pump must be reprogrammed in order for proper drug infusion to resume

- At least 20 minutes after completing MRI exposure interrogate the pump using the clinician programmer:
  - select the check box to download event logs (see Appendix 2), press “OK”
  - close the status screen by pressing “X” in the top right corner
  - select the toolkit icon (the last tab on the top of the screen)
  - select event log (the last subtab) and press “OK”
- If the event log states “Motor Stall Occurred” and “Motor Stall Recovery Occurred”, normal function of the pump has returned (see Appendix 4)
- If event log does not show stall and recovery, wait 20 minutes after the initial interrogation, re-interrogate the pump using the clinician programmer, and review the event logs again. This will address the potential for event logging delays due to Electromagnetic Interference (EMI) from the MRI magnetic field
- If the event log states “Motor Stall Occurred” and does not state “Motor Stall Recovery Occurred”, there is a potential for an extended motor stall due to temporary gear binding. Contact Medtronic Technical services for further troubleshooting
- In all other cases, the pump has resumed its normal operation.

4.10 Post-Mortem Pump Explant

- Contact Medtronic to obtain code (which is date and device specific) to stop and silence intrathecal pump permanently
- If the body is to be cremated the pump must be explanted because the pump will explode at high temperatures.

5. DOCUMENTATION

- Intrathecal prescription and pump refill record (excluding cytotoxic medications)
- Medical record
- Implant MRI Compatibility Check, MRI Department.

6. AUDIT

N/A

7. REFERENCES

- Assessing Intrathecal Drug Delivery Systems with $^{99m}$ Technetium – DTPA Radiotracer Imaging – Personal Communication
- NSW Health PD2014_036 - Clinical Procedure Safety
8. REVISION AND APPROVAL HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision No.</th>
<th>Author and Approval</th>
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<tr>
<td>Nov 2009</td>
<td>1</td>
<td>Susie Kerr NM Pain Management in consultation with SESIAHS Senior Pain Management Nursing and Medical Staff</td>
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<tr>
<td>Feb 2010</td>
<td>1</td>
<td>Forwarded to “Draft for Comment” for consultation / feedback</td>
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<td>Mar 2010</td>
<td>1</td>
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<td>Jul 2010</td>
<td>1</td>
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<tr>
<td>Jun 2013</td>
<td>2</td>
<td>Amendments made by Grazyna Jastrzab NM Pain Management in consultation with SESLHD Senior Pain Management Nursing and Medical Staff</td>
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<td>Aug 2013</td>
<td>2.5</td>
<td>Amendments made by Grazyna Jastrzab NM Pain Management in consultation with relevant SESLHD Senior Management Nursing and Medical Staff</td>
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<td>Oct 2013</td>
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<td>Jun 2014</td>
<td>2.5</td>
<td>Page Number for Chronic Pain Nurse updated as requested by Author.</td>
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<tr>
<td>Feb 2016</td>
<td>3</td>
<td>Review undertaken – Approved by Executive Sponsor, Dr Gregory Keogh.</td>
</tr>
<tr>
<td>August 2016</td>
<td>3</td>
<td>Submitted to Quality Use of Medicines Committee for approval</td>
</tr>
<tr>
<td>October 2016</td>
<td>3</td>
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<tr>
<td>November 2016</td>
<td>4</td>
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<td>December 2016</td>
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<td>Endorsed by Quality Use of Medicines Committee</td>
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Appendix 1
Checklist for patients with implanted intrathecal system requiring MRI at POWH

1. **Referral to MRI - Referring MO to consider the following**

<table>
<thead>
<tr>
<th>Description</th>
<th>Yes/No</th>
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<tbody>
<tr>
<td>The MRI is not using greater than 1.5 Tesla horizontal, closed-bore scanners</td>
<td></td>
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<tr>
<td>The pump is not oriented 90° with respect to the z axis of the MRI scanner</td>
<td></td>
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<tr>
<td>(see appendix 2)</td>
<td></td>
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<tr>
<td>The patient can safely be deprived of drug delivery</td>
<td></td>
</tr>
<tr>
<td>No need for alternative delivery methods for the drug during the time required for the MRI scan</td>
<td></td>
</tr>
<tr>
<td>No medical supervision required while the MRI is conducted</td>
<td></td>
</tr>
<tr>
<td>Details are provided of the type of implant, manufacturer, make, model and serial number for compatibility check eg, SynchroMed® II models, 8637-20 (20mL) or 8637-40 (40mL) or IsoMed model: 8472-35-05 35mL @ 0.5mL/day or, 8472-60-10 IsoMed @ 1.0mL/day</td>
<td>Yes/No</td>
</tr>
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2. **Appointment for MRI is made. Patient completes MRI surveillance form.**

   Patients with **Medtronic SynchroMed® II pump** must have the appointment made on days when pain clinic is open, to allow for interrogation of the pump post the MRI scan.

<table>
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<th>Booking officer</th>
<th>Yes/No</th>
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<tr>
<td>The anticipated completion time of MRI scan is: Tuesday 13.30-15.30, Wednesday 8.30-15.30 or Friday 8.30-10.30</td>
<td></td>
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<tr>
<td>One of the following nursing staff has been contacted to confirm suitability of appointment (day and time): Chronic Pain Nurse p.45228, Clinical Nurse Consultant p.44378 or Nurse Manager p.44642</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

**Pain Nurse**

<table>
<thead>
<tr>
<th>Description</th>
<th>Yes/No</th>
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<tbody>
<tr>
<td>Appointment documented in the Pain Clinic planning diary</td>
<td></td>
</tr>
<tr>
<td>Patient’s medical records ordered</td>
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3. **Post MRI scan**

<table>
<thead>
<tr>
<th>MRI Nurse</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>One of the following nursing staff has been contacted and notify about time patient’s scan was completed: Chronic Pain Nurse p. 45228, Clinical Nurse Consultant p.44378 or Nurse Manager p.44642</td>
<td></td>
</tr>
<tr>
<td>Patient directed to PainClinic in Outpatient Department POWH</td>
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**Pain Nurse**

<table>
<thead>
<tr>
<th>Description</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interrogates the pump at least 20 min post MRI.</td>
<td></td>
</tr>
<tr>
<td><strong>Note:</strong> there is a potential for a two to 24 hour delay in return to proper drug infusion after completion of an MRI scan</td>
<td></td>
</tr>
<tr>
<td>Motor stall and recovery detected and documented</td>
<td></td>
</tr>
<tr>
<td>Infusion rate checked against previous documentation in medical records</td>
<td></td>
</tr>
</tbody>
</table>

If the answer to any of the above is **NO**, the issue needs to be discussed with the referring MO.
Appendix 2

Pump positions in relation to z-axis MRI orientations
Appendix 3

Press the "Interrogate" button

Select "Logs" check box in the option window that opens

Event Log section

stall recovery on 2/18/2006 at 13:09
stall detected on 2/18/2006 at 12:30