Royal Cornwall Hospitals
NHS Trust

Intrathecal Pump / Implantable Medical Device for Cancer Pain and Spasticity Standard Operating Procedure

V1.0

April 2025

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1. Introduction

1.1. An Intrathecal drug delivery (ITDD) system is implanted for patients with cancer related pain that are not adequately controlled on escalating doses of opioids or that are experiencing unpleasant intolerable side effects. An Intrathecal drug delivery system is also sometimes implanted for patients with spasticity that had a positive trial of intrathecal baclofen. This document focuses mostly on cancer pain patients, but principles apply to spasticity patients.

1.2. ITDD systems are an advanced stage intervention and are only indicated where other conservative interventions have failed or are contraindicated and where the uncontrolled pain is causing a significant impact on physical and mental health

1.3. An intrathecal system will generally be implanted for those patients with a life expectancy greater than 6 months, although exclusions may apply. This is supported by the NHSE Clinical Commissioning policy: Intrathecal Pumps for Treatment of Severe Cancer Pain ref D08/P/b https://www.england.nhs.uk/wp-content/uploads/2018/07/Intrathecal-pumps-for-treatment-of-severe-cancer-pain.pdf This policy is currently under review and draft version currently reads: “ITDD is used equally in patients with limited life expectancy as those patients with near normal expectancy.”

1.4. Currently, devices are manufactured by Medtronic. Synchromed III is the current model in use. It is available as a 20ml or 40ml reservoir. This contains the drug which is infused continuously into the cerebrospinal fluid (CSF) and a power source that drives the pump. Most patients will be implanted with a 40ml pump for the practicalities of refill scheduling. The pump is implanted into the abdominal wall. A silicone catheter is inserted into the CSF, usually in the lumbar region, and anchored in place. A catheter tunnelled subcutaneously around the abdominal wall connects both parts.

2. Purpose of this Standard Operating Procedure

2.1. The purpose of this document is to set out a pathway for Pain Service patients identified as suitable for Intrathecal implant. This will identify responsibilities of nominated / key staff involved for the smooth process of appropriate patient selection through to timely and safe implantation and follow up appointments for planned refills and unscheduled reviews if necessary.

2.2. Improve quality of life of patients with identified need.

The process for those patients with post implant complications, and those patients who require routine intrathecal pump/system replacement are detailed.

3. Ownership and Responsibilities

3.1. This pathway has been drawn up by the multidisciplinary team involved in care, administration, and planning. Managers and Care group senior leadership aware of existing service and historical context. This iteration is an attempt to formalise what has been done for many years at this Trust.

Service managers are responsible for:

- Availability of planned appropriately staffed theatre space with laminar flow or air exchange of sufficient quality to allow central nervous system implants. Current theatre utilisation is St Michael's Hospital, Hayle, one afternoon list per month. Availability of inpatient bed at St Michael's Hospital, Hayle.

3.2. Role of the Pain Implanting Consultant (Implanter)

- Named consultant for the patient who has overall responsibility for the ongoing care of the patient. This will be the implanting consultant.

- Effective screening/ selection of appropriate patient for implantation, explaining procedure, risks and complications. Advice on medication changes, cessation of cancer treatment drugs and anticoagulation prior and post implantation.

- Competence in the procedure of implantation of intrathecal catheter, medical device / pump, and any necessary revision surgery.

- Agreement between team of consultants planned to attend implant list as per implant list rota. Main implanter and assistant. Also discussed at department monthly MDT.

- Ordering of prescription from pharmacy technical services on Maxims correspondence.

- Competence in the procedure of pump refill.

- Availability for troubleshooting advice for ongoing management.

- Rota planning agreed between consultant members and effective handover to cover episodes where continuity will reduce e.g. annual /study leave.

- Liaison with Palliative Care/ Oncology consultants.

- Completion of National Neuromodulation Registry (NNR) entry with pump details and patient's demographic. Requires patients' consent.

3.3. Role of the Pain Consultant (Non-Implanter)

- Awareness of this treatment modality and screening of potential patients as part of their Combined Palliative Care / Pain Clinic.

- Availability and support to troubleshoot unexpected complications as part of their on-call commitments for Pain rota (Consultant on call for the week).

- If desired, could continue to provide continuity of care for patients they have selected with regards to medication advice (discontinuation of oral medication for example).

3.4. Role of Specialist Nursing staff

- Competence in education and advising patients of pathway, intrathecal implant, and post operative management.
- Baseline information and questionnaires for National Neuromodulation registry NNR (requires patient consent).
- Education to other staff groups involved in the care of patients with ITDD medical device.
- Liaison with administration staff for ordering of necessary equipment, pump, catheter, revision kits, myPTM (Medtronic).
- Ordering from pharmacy of any additional medications for implant and appropriate refill equipment kits, fibrin glue (Veraseal/Tisseel), etc.
- Undertaking MRSA screening/providing 4% Chlorhexidine wash. Octenisan wash if sensitive to Chlorhexidine.
- Requesting appropriate bloods (FBC/U&E's, CRP, HBA1c) via pre op request on Maxims and refer to pre-operative assessment unit.
- Liaison with company representatives to attend implantation list.
- Maintenance of stock lists for non PBR return.
- Maintenance of database/records. Update request to maxims team to request addition of spinal implant alert.
- Availability of specialist nursing support to the patient for general advice, pain management, technical queries, MRI requests.
- Competence in undertaking refill of implanted medical device with appropriate training.

3.5. Role of the Administrative Staff

- Booking of clinical appointments on booking system / PAS. S:\TR15\Anaesthetics\Clinics\Pain Secretaries\Secretarial SOP.
- Add patients to theatre list on Galaxy.
- Ordering of necessary equipment.
- Booking via email of inpatient bed at St Michael's hospital/ liaison with Hospice if inpatient. Liaison with admin teams re: transport when required.
- Monthly return to finance team.
- Ensuring switchboard have an updated rota for the Pain Consultant on call. The acronym VOTW is sometimes used to describe this role.

- Copy of Pain Consultant on call rota sent via email to St Julia’s and Mount Edgecumbe Hospices.

3.6. Role of Pharmacy Technical Services

Preparation of intrathecal syringes and delivery to appropriate pharmacy (Treliske or St Michael’s Hospital at present).

4. Standards and Practice

4.1. **Exclusion criteria**: absolute contraindications are: pregnancy, nursing mother or planning to get pregnant. Any concomitant treatment or medical condition that would render ITDD administration hazardous.

Patients who have spinal anomalies, extensive spinal metalwork preventing the insertion of device or insufficient body mass. Coagulopathy which can’t be corrected, sepsis or active infection, allergies to silicone, titanium or the medications used in the implantable medical device. Skin infections of the back or anterior abdomen. As a general guide any of the following infection risk markers unmet: CRP below 10 mg/L, HbA1c ideally below 53 mmol/mol, certainly below 61 mml/mol (risk/benefit of infection and need for device to be discussed with individual patients). History of psychosis, (caution with ziconotide, active suicidal or homicidal behaviour, major uncontrolled depression, or anxiety, or serious cognitive deficits. These conditions should be treated or optimised first. Ensure up to date Body Mass Index (BMI) is calculated, this should ideally be below 35.

4.2. **Implantation Criteria**: Patients referred and seen in combined pain/palliative clinic/ hospice by Pain Consultant and/or Palliative Care Consultant. Spasticity patients are referred and co-managed by the neuro-rehab team. Pain that is not responding well to escalating doses of opioids or patient experiencing significant side effects from oral medication. Cancer related pain in an amenable anatomical location. The patient commits to attend for reviews, dose adjustments and top up of reservoir. Agreement to proceed once discussed at MDT.

4.3. **Pathway:**

- Decision to proceed? Yes/no.

No: supportive care with palliative/hospice team.

Yes: Information and consent – Consultant.

- Pump information session, MRSA screen / wash given – ANP.
- Pre-operative assessment and bloods requested. Refer to anaesthetic pre-operative assessment – ANP.
- MRSA status and VTE requirements known. – ANP.

- Analgesia conversion – Implanting Consultant with Palliative team.
- Timing of stopping chemotherapy and plan for anticoagulation- Implanting Consultant with Oncology team.
- Equipment to be ordered – ANP/Admin.
- Consultants agree on who will attend list – planned – Consultant.
- Company representative to be booked – ANP.
- Booked to Galaxy theatre list - P2 category – Admin.
- Bed and overnight stay booked at St Michael's hospital. – Admin.
- Intrathecal drugs/syringe to be ordered for delivery to St Michael's hospital – Consultant.

4.4. Perioperative:

- Laminar flow / well-ventilated theatre and strict sterility.
- X-ray availability Radiographer (familiar with fluoroscopy for pain procedures).
- Agreed kit list: pump, catheter and syringe.
- Reduced footfall in theatre – team brief prior to procedure start with no interruptions.
- Sign on theatre doors specifying high risk implant procedure in progress.
- Fibrin glue (Verseal/Tisseel). Non NRFit loss of resistance syringe.
- Pump programmer.

4.4.1. In theatre: procedure method:

Sterile items required - Medtronic SynchroMed III pump package which includes:

- Implantable drug pump, 22-g non-coring needle (for filling the pump), 24-g non-coring needle (for flushing the catheter access port).

Medtronic Ascenda™ model 8780 or model 8781 intrathecal catheter and Medtronic catheter passer.

4.4.2. Clinician-supplied items:

- 20mL syringes x 2 (for emptying the pump).
- Syringe containing the prescribed fluid drawn up through a filter needle or intrathecal syringe pack for preparation in theatres, 0.22-micron filter.

4.4.3. Non-sterile items:

- Medtronic Synchromed III programmer.
- myPTM - Patient Therapy Manager (if required).

4.4.4. Patient preparation

- Identify the pump site, mark patient whilst in sitting/supine position. This should be carried out in the admission area before transfer to theatre suite.
- Position the patient in lateral decubitus position, prep from axilla-pubis, table-to-table, drape widely and cover the skin with Opsite drape.

4.4.5. Prepare the pump for implant

- Check pump status, including the serial number and calibration.
- Empty the pump: Remove the protective cap; assemble the 22g non-coring needle and syringe, insert into the reservoir fill port septum until the needle touches the metal; maintain negative pressure to withdraw the sterile water from the pump into the empty syringe.
- Empty the reservoir completely, until air bubbles stop flowing into the syringe. Maintain negative pressure on the syringe as needle is removed from the septum.
- Attach the 22-gauge non-coring needle to the syringe containing the prescribed fluid and filter and purge the air from the needle.
- Filling the pump to capacity will bring the expected concentration to about 93%.
- Rinsing the pump with 3 mL of the drug will result in a concentration of about 98%.
- Rinsing the pump with 10 mL of the drug will result in a concentration of about 99%.
- Discard the 3 mL or 10 mL of the drug used to flush the pump, and fill the pump with the remaining drug.
- Use the actual fill volume (initial volume in the syringe less the 3 mL or 10 mL used for rinse) when entering information into the programmer.
- Insert the needle into the reservoir fill port septum until it touches the metal needle stop. Slowly inject the prescribed fluid into the pump reservoir at a rate of no more than 1 mL per 3 seconds.
- Flush the catheter access port with 1-2ml of sterile water.

4.4.6. Catheter insertion

- Insert spinal needle lateral oblique approach 1-1.5 vertebral levels below/above dural entry point. Confirm CSF flow, replace stylet until spinal segment catheter inserted to desired level, and verify catheter position using fluoroscopy.

- Extend incision to prepare anchor site, place 2 sutures one either side of catheter insertion point plus one purse-string suture whilst needle still in-situ. Hold catheter securely and remove needle and guidewire from catheter. Clamp catheter with rubber/gauze-tipped clamp.

- Apply inject anchor and dispense with anchor head beneath fascia, and wings on fascia. Tie sutures to anchor wings.

- Apply fibrin glue (Veraseal/Tisseel) prior to securing anchor.

- Prepare the pump pocket.

- Tunnel the pump segment catheter from pump pocket to spinal insertion site.

- Attach connector securely to pump segment.

- If desired, trim spinal catheter segment to leave 5cm outside of fascia or leave catheter untrimmed. **Note how long trimmed segment is to calculate volume of residual catheter. This will be used in the calculation for catheter priming**.

- Confirm CSF flow through catheter to end of pump segment.

- Attach pump to sutureless pump connector.

4.4.7. Place and suture pump in pocket

- Position pump at appropriate depth from skin, ensure pump access port is uppermost, and no loops of catheter lie anterior to pump. Ensure catheter is not kinked and at least one loop lies beneath pump.

- Irrigate both pocket and spinal wounds. Suture in 2 layers with Vicryl and Monocryl or Prolene and clips.

- Wounds should be covered with an adequately sized dressing.

4.4.8. Record patient information:

- Labels from implanted medical devices label will be required for the theatre register, patient with the patient’s name and identification number.

- Place the Patient Manual and identification record (Pain Procedures form) and returned for administration staff to reconcile equipment inventory for finance.
- This information is also required for the National neuromodulation record (N.N.R) and Pain Service neuromodulation database.
- Be sure the following information is also recorded in the patient's file:
  - Date of implant.
  - Catheter model number.
  - Catheter sterile lot number.
  - Implanted catheter length.
  - Drug name, concentration, and volume.
  - Daily drug dose.

Label the Patient Manual card to accompany the patient into the recovery room.

- Intrathecal medication check: Both the nursing staff and implanting consultant (or assistant) will check the aseptically prepared drug against the prescription and the patient prior to commencing the operation.
- The drug will be checked again with the prescription at the time of filling the IT pump immediately prior to implantation into patient.
- The nursing staff and the Medtronic representative will programme the Synchromed III pump as necessary to include the patient's details, the equipment specifications and prescription requirements. New implants require programming a priming bolus, medication bolus, background daily rate plus my PTM (Patient Therapy Manager) doses as required.
- During the surgical procedure, a formal break will occur with cessation of all theatre activity whilst the IT pump program is checked by both the implanter and assistants.
- The patients handheld document should be completed with the serial numbers of all equipment used during the operation, the catheter lengths implanted, the medications and the dosing regimes.
- Print outs of the program information will be made available on the department's shared drive **S:\TR15\Anaesthetics\Clinics\~PAIN SERVICE - DOCUMENTS\Implanted Spinal Devices\Patient printouts pumps.**
- A planned date should be provided to the patient for next refill.

4.5. **Post operative**:

- Immediate care in hospital – observations, lie flat for 6-8 hours, analgesia plan, post op instructions for ward staff (including VTE prophylaxis).

4.5.1. Discharge: home-

- Patient information and post operative instructions.
- myPTM instruction if applicable.
- Complications and what to do if? Who to call if needed? (in and out of hours).
- Date for wound closure suture / clips removal or wound check.
- Date for top up to be arranged after initial 2 weeks of titration.
- When to restart chemotherapy and/or anticoagulation?

4.5.1. Discharge: hospice-

- Hand over to be written and verbal (if possible) -handover sheet completed by ANP in theatre and given to patient for Hospice staff.
- Post op care and observation.
- Post op medications and ongoing plan.
- Complications and who to call (in and out of hours).
- Date for wound closure suture / clips removal or wound check.
- Date for top up.
- When to restart chemotherapy and/or anticoagulation.

4.6. **Follow up and ongoing care**:

- Patients will be notified of how to contact the Pain Clinic for any queries arising regarding the management of their intrathecal implanted device. Any enquiries should be directed to the Pain Clinic Mon-Fri 01872 252160 / 252792. At weekends or out of hours, they should contact via switchboard 01872 250000.
- Information for patients - side-effects, titration. Patients will be informed by their Pain Consultant of what medications are within the ITDD system. They will be informed of their potential effects and side effects. These may vary dependent on the medications and rates of delivery. Plans for refill as noted below.

- The Pain Consultant is responsible for requesting intrathecal syringe for refill in a timely manner. This is undertaken by completion of letter which is copied to the pharmacy technical services team.

- The ANP/ nursing team is responsible for ensuring availability of refill syringe kit in advance of clinic appointment, also for appropriate medications i.e. ziconotide to be available from pharmacy.

- Any supply issues should be notified to the Pain Consultant as far as possible in advance to ensure timely refill.

- Attention should be given to the requirement for intrathecal syringe following a bank holiday, due to the impact of pharmacy technical services closure.

- An implanted drug delivery pump “Alert” should be added to the hospital correspondence system (Maxims)/ Patient Appointment System (PAS). This acts as an alert to hospital teams in case of admission and or need for MRI scanning. The ANP within the Pain Service is responsible for ensuring this is undertaken.

- If a patient requires an MRI then the necessary documentation will be completed by the ANP. The patient should attend clinic following the MRI scanning appointment to ensure no rotor arm stall occurred which would affect the drug delivery.

4.7. **Significant complications pathway**:

- Who to contact and details.

    - During office hours, patients to contact the Pain Clinic in the first instance. Admin / ANP’s staff will then contact primary implanter, assistant or consultant on call via email rcht.votw@nhs.net.

    - Out of hours, patients to present to the Emergency department if there is a high suspicion of cauda equina or meningitis. ED staff to contact pain consultant on call via Switchboard. Referral to pain consultant should be from CT3, staff grade or above.

- Pain not controlled, side-effects. May require unscheduled attendances to the Pain Clinic for titration of medication (up or down).

- Infection – treatment, explant. Patient to contact Pain Clinic as above. If high suspicion of infection patient to contact GP via 111.

Infections of intrathecal pumps can be superficial but can also progress to meningitis or deep infections such as epidural or cerebral abscess. This can be life threatening or cause serious neurological injury. Prompt and effective treatment should be instituted to reduce this risk whilst also balancing the need for analgesia for these patients with palliative cancers.

For intrathecal devices in non-cancer patients the reported infection rate is 2-8%. In Cancer patients who are immunosuppressed receiving steroids, radiotherapy, chemotherapy the rate will be higher. In related procedures such as cancer related breast procedures the infection rate is 3-15%.

Infections are generally post-surgical, or late presumably from seeding of systemic infective organisms. Another source is from refills.

4.8. High Risk Groups

- The presence of sepsis/ infection is a relative contra-indication. Rarely individual patients with controlled chronic infection can be implanted - these are high risk.
- Refills should be avoided when patients have infections. However, it may be necessary in some cases. A refill done in the presence of infection is also high risk.
- Cancer patients, steroid therapy, diabetics, recent radiotherapy / chemotherapy, low cell counts, multiple co-morbidities, elderly.

4.9. Identification

- Infection commonly present from 2 days to 6 weeks following implantation, however late infection is still possible even years following implantation and may be secondary to refills.
- At every patient contact patient should be screened for signs and symptoms of infections.
- Signs/ Symptoms include:
  - **Systemically unwell** - Feeling unwell/ hot/ excessive sweating/ nausea/ vomiting.
  - **Surgical sites -** New pain/ redness/ swelling/ Heat/ Pus.
  - **Meningism/ Overt Meningitis** - Headache, photophobia, neck stiffness.
  - **Neurological impairment (epidural haematoma/abscess)** - Impaired GCS, unequal pupils, sensory changes/motor weakness in lower limbs. Incontinence of urine or faeces/ perineal numbness. Will require admission through Derriford neurosurgical team.
  - **Unstable** - Pyrexia/ tachycardia/ tachypnoea/ low blood pressure.
- **Differential Diagnosis**
  - **Infections.**
  - ❖ Superficial infection.
  - ❖ Necrotising fasciitis.

- ❖ Pocket infection.
- ❖ Tracking infection.
- ❖ Epidural infection/ Abscess.
- ❖ Cerebral abscess.
- ❖ Meningitis/ Encephalitis.

- **Other Intrathecal pump related issue:**

- ❖ CSF leak.
- ❖ Seroma/ Haematoma.
- ❖ Catheter migration, occlusion, fracture.
- ❖ Granuloma.

- **Non-pump related issues:**

- ❖ Disease progression.
- ❖ MSK pain.
- ❖ UTI / Chest Infection.
- ❖ Other.

4.10. Specialist Nursing /ANP staff should infection is suspected

- Record patients reported symptoms.
- Enquire about meningism - headache/ neck stiffness/ photophobia/ unwell.
- Enquire about cauda equina - there is no new weakness in legs or incontinence of urine or faeces.
- Take observations Pulse /BP/Temp/Sats/RR.
- Take wound swab if there is pus.
- Take bloods FBC/U+Es/CRP.
- Take blood cultures if high suspicion/ pyrexial.
- If the source is possibly from refill – sample should be taken from reservoir for culture.
- Inform the consultant who implanted the system immediately after assessment, if they are not available inform the on-call consultant or if not available any available pain consultant.

4.11. Action for medical staff

- Assess patient.
- Ensure all relevant microbiology samples are being sent (is pump reservoir culture required?).
- Consider the need for antibiotics (refer to current Trust guidelines).
- Current advice is flucloxacillin 1g QDS.
- If penicillin allergy or MRSA, seek Microbiology advise.
- Is necrotising fasciitis suspected?
- Consider discussing with microbiology.
- Consider the need for admission for lumbar puncture.
- Consider the need for referral to neurosurgical team – Derriford.
- Consider removal of system and alternative analgesic plan.
- Consider continued management.
    - This will be a triaged response based on communication with either patient, hospice team, Palliative CNS and/or Pain Consultant. First line admission to clinic to be arranged by ANP. Blood screening FBC, CRP and U's& E's, Routine vital signs observations should be undertaken. In event of pyrexia, blood cultures are required. If admission required for IV antibiotic administration, patient may be admitted under medical team via Same Day Medical Admission unit or via the General Surgical take if further surgery is needed. Contact may need to be overseen by the site coordinator regarding inpatient bed (contact via switchboard) and or Manager of the Day (contact details available on CLW rota). Pain Consultant to contact Medical Registrar or Surgical Registrar / Consultant on call.
    - In the event of Intrathecal Explant this needs to be organised by a Pain Consultant (on call, primary implanter or assistant) and general surgical team as above. Patient requires admission to ensure emergency theatre can be booked. Admission documentation to be completed by medical or surgical resident team (clerking, routine medication prescription, further investigations if required).
    - Dural headache. Attempt conservative measures (bed rest, iv fluids, caffeine). If blood patch required, to be admitted under medical team via Same Day Medical Admission unit. Contact may need to be overseen by the site coordinator regarding inpatient bed (contact via switchboard) and or Manager of the Day (contact details available on CLW rota). Pain Consultant to contact Medical Registrar on call.

- Pump malfunction – contact pain clinic ANP who will liaise with company representative.

Refill of intrathecal pump and dose adjustments:

Refill appointments will be booked on PAS/ outpatient booking system. These are notified to the patient by online booking system- Patient Hub. This information is also detailed in the clinic letter which is copied to the patient and their GP. **NB** Patients are reminded that they should not routinely cancel these appointments due to either being unwell or for other reasons, without liaising with the Pain Clinic admin team and Pain Consultant. There may be occasions that the patient will need to attend for dose adjustments in between planned refill appointments. These will be booked as noted previously. Patients are encouraged to contact the Pain clinic to discuss any issues with their pain management that can't be resolved by their community palliative care nurse or palliative care consultant.

Pain clinic administration staff should ensure that a PAS notification is added against the clinic appointment stating that it is for a refill / top up and should not be cancelled.

Care in the "dying phase" – patients may be admitted to hospice. Liaison with staff re additional requirements e.g. ketamine infusion. Palliative care consultants to liaise with Pain Consultant on-call to agree an escalation plan.

Cremation information – ITDD systems (pump) needs to be removed prior to cremation. Hospice staff familiar with explantation of pacemakers. Follow similar pathway.

4.12. Management of post-operative complications

Seromas

Seromas may be evident by the first postoperative day. Signs and symptoms of seromas include swelling over the pump site and/or feeling of tightness over the pump site. Pocket seromas often resolve without treatment, but may persist for days or, in some cases, weeks. Aspiration may be necessary if the seroma is painful, or the wound is at risk for dehiscence. Always evaluate the risk of infection. After aspiration, a compression dressing or abdominal binder may decrease the risk of re-accumulation.

Spinal Epidural Haematoma

For patients with low platelet counts—at high risk for postsurgical bleeding—follow standard medical practice for patients on anticoagulant therapy. Epidural hematomas are rare but could produce severe complications. Watch for signs of epidural haematoma: severe back pain, sudden onset of leg weakness and spasm, loss of reflexes in the distal extremities, and loss of bladder/bowel control. An epidural haematoma is an emergency and must be given immediate attention.

Bleeding

For patients at higher risk for post-surgical bleeding with low platelet counts, follow standard medical practice for preoperative/postoperative management of patients on anticoagulant therapy.

Spinal Headaches

Watch for subcutaneous cerebrospinal fluid leakage at the incision site, along the catheter, and in the pump pocket site. Surgical re suturing or revision may be necessary. Spinal headaches may be caused by cerebrospinal fluid leakage around the catheter, or loss of cerebrospinal fluid during the implant procedure. A preventive measure includes instructing the patient to lie flat overnight immediately following surgery. This greatly reduces the risk of spinal headache. If a headache still occurs, the patient should continue to lie flat for 1 to 2 days. Consider oral analgesics to reduce the pain. Caffeine in some over-the-counter pain medications may relieve the headache. Check for cerebrospinal fluid leakage if pain persists beyond a few days. If the spinal headache persists, consider performing a blood patch. A blood patch involves the injection of 10 to 15 mL of the patient’s own venous blood into the epidural space to seal the epidural puncture. The blood patch should be performed under fluoroscopy. CSF leak or drainage from the spinal incision is an emergency and must be given immediate attention.

Infections

Watch for signs and symptoms of infection: redness, pain, and swelling. Any leak from the wound should be closed immediately to avoid contamination of the implanted system. Infections should be treated aggressively with systemic antibiotics. Delay in treatment can lead to meningitis and/or pump explant. Consider seeking advice from Microbiology to determined choice of IV antibiotics. These antibiotics should differ from the peri-operative antibiotics to ensure that all gram-positive organisms are treated. Purulent drainage from the wound or erythema (redness) of the pump pocket or catheter insertion site should be considered an emergency. The patient should be placed on intravenous antibiotics. If infection persists, the pump and catheter should be removed, and the CSF should be evaluated for meningitis. Aggressive treatment of withdrawal should begin prior to pump removal and continue in the post-operative period.

Incision Pain and Discomfort

Pain and discomfort around the incision sites and the area in which the catheter is tunnelled are common complaints following surgery. Observe for bleeding or wetness on incision dressings over the pump and catheter insertion site. Change sterile dressings on both incision sites per hospital policy. The duration and intensity of pain varies by individual. Provide additional analgesia as needed.

Spinal Hygromas

Spinal hygromas present the following characteristics: Swelling typically found under the skin in the lumbar region of the back result from leakage after the intraspinal catheter implantation and are typically small and self-limiting (tend to disappear on their own without treatment).

Management: Consider using an abdominal binder with pressure dressing at the spinal site immediately post-op. Hygromas may be aspirated; evaluate risk of infection before aspirating.

4.13. System-related complications

- Cessation of therapy due to end of device service life or component failure
- Change in flow performance characteristics due to component failure
- Inability to program the device due to clinician programmer failure or loss of telemetry
- Catheter access port failure due to component failure. Refer to Medtronic manual.
- Local and systemic drug toxicity and related side effects
- Complications due to use of drugs not approved or formulated for intraspinal delivery (formulations should be sterile and preservative-free)
- Complications due to using drugs not in accordance with drug labelling
- Inflammatory mass formation at the tip of the implanted catheter in patients who receive intraspinal morphine or other opioid drugs (Granuloma). This tends to be a delayed complication seen in non-cancer patients. Less likely to be an issue.

4.14. Procedure-related complications

The procedure-related adverse events associated with the use of this system may include, but are not limited to, the events that follow:

- Inaccessible reservoir fill port due to pump being implanted upside down (inverted) or too deep
- Pocket seroma, hematoma, erosion or infection
- Post lumbar puncture (spinal) headache
- CSF leak leading to CSF subcutaneous collection or rare central nervous system (CNS) pressure-related problems
- Radiculitis, Arachnoiditis, Meningitis
- Bleeding

- Spinal cord damage
- Medical complications, Anaesthesia complications
- Damage to the pump, catheter, and catheter access system due to improper handling and filling before, during, or after implantation
- Infection, Reservoir contamination

4.15. **Catheter-related complications**

- Change in catheter performance due to catheter kinking, catheter disconnection, catheter leakage, catheter breakage, complete/partial catheter occlusion, catheter dislodgement or migration, catheter fibrosis or hygroma
- Detached catheter tip or catheter fragment(s) in the intrathecal space:
- Residual catheter fragments may migrate, including rarely into the intracranial cavity, potentially resulting in serious adverse health consequences that may require surgical removal.
- Residual catheter fragments in the CSF may compromise antibiotic effectiveness in the presence of a concomitant CSF infection.

5 Dissemination and Implementation

5.1 The associated nursing documentation is available on the document library and will be made available to hospice staff as patients will be cared for in this location as well as in hospital. Significant updates will be communicated via Trust wide email.

5.2 Implementation of the procedure and provision of training and support for staff will be undertaken by the Pain Clinic for the relevant members of staff.

6 Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Appropriate patient selection and smooth process to implantation. NHSE guidelines. National neuromodulation registry (NNR) and Pain Services Implantation Database.
Lead	Specialty ANP / Lead Consultant for pain implanted devices.
Tool	**https://neuromodulationregistry.org/** Medtronic Manual. SynchroMed™ IsoMed SynchroMed™ IsoMed SynchroMed™ IsoMed SynchroMed™ IsoMed SynchroMed™ IsoMed - Implantable infusion systems Systèmes de perfusion implantables Implantierbare Infusionssysteme Implanteerbare infusiesystemen Sistemi di infusione impiantabili

Information Category	Detail of process and methodology for monitoring compliance
Frequency	Monthly MDT discussion and annual report
Reporting arrangements	Pain Services
Acting on recommendations and Lead(s)	Pain Services department will be responsible for making any recommendations, these will be documented within the minutes of monthly governance meeting and joint pain and palliative meeting.
Change in practice and lessons to be shared	Any changes to practice will be agreed by Pain Services MDT and relevant staff would be informed by email.

7 Updating and Review

7.1 The document review process is managed via the document library. Document review will be every 3 years unless best practice dictates otherwise. The author remains responsible for the policy document review. Should they no longer work in the organisation or in the relevant practice area, then an appropriate practitioner will be nominated to undertake the document review.

7.2 Revision activity will be recorded in the version control table to ensure robust document control measures are maintained.

8 Equality and Diversity

8.1 This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

8.2 Equality Impact Assessment. The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Intrathecal Pump/ Implantable Medical Device for Cancer Pain and Spasticity Standard Operating Procedure V1.0
This document replaces (exact title of previous version):	New Document
Date Issued / Approved:	March 2025
Date Valid From:	March 2025
Date Valid To:	March 2028
Author / Owner:	Dr J Graterol- Consultant in Anaesthesia and Pain Medicine. Kate Fleming – Advanced Nurse Practitioner chronic pain. Jayne Thomas - Advanced Nurse Practitioner chronic pain.
Contact details:	01872 252160
Brief summary of contents:	Standard Operating Procedure (SOP) covering the pathway and management of patients being implanted with an intrathecal medical device.
Suggested Keywords:	Intrathecal, Palliative Care, Pain, Opioid, Spasticity.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Care Group Governance
Manager confirming approval processes:	Dr Russ Evans
Name of Governance Lead confirming consultation and ratification:	James Masters, Governance Lead, ACCT

Information Category	Detailed Information
Links to key external standards:	None
Related Documents:	None
Training Need Identified:	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pain

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
20/01/2025	V1.0	Initial issue	Dr Graterol Consultant in Pain Medicine and Anaesthesia. Kate Fleming ANP/ Jayne Thomas ANP Chronic Pain - Pain Service.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing. Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Intrathecal Pump / Implantable Medical Device for Cancer Pain and Spasticity Standard Operating Procedure V1.0
Department and Service Area:	Pain Services, ACCT
Is this a new or existing document?	New
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Kate Fleming, Advanced Nurse Practitioners, Chronic Pain, Pain Services
Contact details:	01872 252160

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide information and structure to the planning and provision of intrathecal / implantable medical devices for Cancer Pain and Spasticity both for care at RCHT and Hospice settings.
2. Policy Objectives	Ensure safe practice
3. Policy Intended Outcomes	Safe management of patients and timely provision of excellent pain control and management for those with cancer pain experiencing unmanageable side effects or those with severe spasticity unmanaged on oral medications.
4. How will you measure each outcome?	Audit
5. Who is intended to benefit from the policy?	Cancer patients under the combined service of Pain Clinic and Palliative care team.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: Yes • Local groups/ system partners: Yes • External organisations: Yes • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Consultants in Pain Medicine and Anaesthesia.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	**(Yes or No)**	**Rationale**
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Kate Fleming AP Pain Services.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis