**Frankston Pain Management** **Suite 7, 20 Clarendon St, Frankston, Vic, 3199**
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## Spinal (Intrathecal) Drug Pump Trial and Implant – Patient Information Consent and Request Form

Many patients with chronic pain are prescribed strong morphine-like drugs to control their pain and continue to take these successfully for many years, but often patients find that these drugs only take the edge off their pain and/or cause troublesome side-effects that are difficult to tolerate. Spinal morphine and similar drugs or baclofen work to relieve pain or spasticity by interfering with spinal cord messaging.

A trial of intrathecal drug therapy and implantation of a drug pump may be considered for some people when conventional treatment is unsuccessful or causes unmanageable adverse effects. The best way to test the ability of these drugs will be helpful is to do a series of test injections with active and inactive medicines.

**Indications:**
The indications for placing an intrathecal drug delivery system are cancer-related pain, noncancer pain conditions, and severe spasticity refractory to other treatment.
Hard-to-manage pain conditions such as; phantom limb pain, complex regional pain, plexopathies, radiation induced pain or post-surgical pain persistent spine pain syndrome refractory to systemic analgesics, co-analgesics and adjuvant therapies or limited by side-effects.
Intrathecal baclofen is indicated in patients refractory to high doses of oral baclofen, tizanidine, or dantrolene.

**Absolute Contraindications**
Patient refusal
Active untreated infection
Severe thrombocytopenia or uncontrolled bleeding disorder
Untreated major psychiatric disorders or psychosis
Active, untreated substance use disorder
Known allergy to implanted materials or medication

**Relative contraindications**
Symptoms unexplained by known pathology
Short life-expectancy – consider a less invasive option with an external pump
Smoking and poor glycemic control have been shown to increase the risk of surgical site infections.
Spinal metastases, canal narrowing or unfavourable anatomy, not allowing safe catheter placement
Other untreated medical problems
Small body size and low BMI are challenges for safe implantation and management
Unrealistic expectations
Cognitive impairment and/or Inability to manage device
Severe obesity due to complexity and increased risk of complications
Inability to reduce oral morphine equivalent dose below 20mg, due to poor outcome
Other: immune suppression, obsessive compulsive disorder
Inadequate social support and poor coping skills
Non-engagement and poor compliance

**RISKS of Spinal Drug Delivery:**
Common to all therapeutic and diagnostic procedures are the usual risks of surgery (~1%).

| Rate | **Biologic Complications/Problems** |
|---|---|
| 1-2% | Wound pain, pocket pain, catheter limb pain. (Usually resolves with further treatment) |
| <5% | No pain relief despite positive trial |
| <0.5% | Nerve damage, spinal cord injury, paralysis, loss of bladder / bowel / sexual function |
| <0.5% | Epidural bleed/haematoma (may need early spine surgery) |
| ~1% | CSF leak and postural headache. |
| 2-5% | Wound Inflammation/haematoma/seroma over devices |
| <0.1% | Allergy to the device or components |
| <1% | Wound breakdown, delayed wound healing(smokers), skin erosion |
| 1% | Meningitis |
| 1-2% ? | Serious/deep infection/abscess (usually requiring system removal and early spine surgery) |
| 1-2% | Superficial surgical site infection (usually settles with antibiotics) |
| ? | Reservoir contamination (refills are done with careful asepsis) |
| | **Device Complications/Problems** |
| 1-6% | Drug pump catheter break, migration or dislodgement (twiddler syndrome) |
| 0-10% | Catheter disconnection or misconnection (needing revision/replacement) |

| | |
|---|---|
| 2-5% | Premature pump failure, flipping preventing pump refill |
| | **Programming or Therapy-related complications** |
| 1% | Drug withdrawal symptoms from program errors or missing a refill. |
| 1% | Pump programming error |
| <1% | Pump refill accidental medication overdose |
| | Pocket refill outside pump |
| | Activation pump over pressure valve |
| 1-2% | Nausea, Vomiting, Constipation |
| <5% | Urinary retention |

**Financial Considerations**
The direct medical and hospital costs may include out-of-pocket gaps for your planned treatment. In addition, please note the possible extra costs for pathology, radiology, recovery (eg rehabilitation) and bills from other medical specialists to anticipate and prevent unexpected problems for your safety.
Your ability to work during the trial and for 2-6 weeks after implanting a permanent device is reduced, which may cause a loss of income for those who are self-employed or don't have enough sick leave.
The cost of complications are difficult to quantify in terms of financial consequences to patients and families. Although most adverse events are self-limited and resolve, severe complications, while rare, may require surgery/procedures, prolonged hospital stay, more time off work than expected and unexpected dependency on family or carers, which may impact on loan repayments and other commitments.

**Informed Consent**
**Get informed!**
Please **read** this **Spinal (Intrathecal) Drug Pump Trial and Implant** - patient information consent form.
Please **watch** video patient information: ?
Please **read**: http://painaustralia.staging3.webforcefive.com.au/static/uploads/files/painaust-factsheet6-final-wffrpjetagnc.pdf
**Check** http://www.fpmx.com.au/solutions.html#treatment-procedures for other options, and
**Check** company websites https://www.medtronic.com/en-us/l/patients/treatments-therapies/drug-pump-chronic-pain.html **for more information**.
**Speak** with a patient ambassador who has a drug pump implanted for a similar problem
**Speak** with the company technician to learn how to live with and manage your device.
**Ensure** your questions and concerns have been answered, be aware of the benefits, limitations and risks

**PREPARATION:**
Please have your teeth checked by a dentist and any necessary work done BEFORE your surgery.
Please see your GP to make sure you are in the best possible health
Please stop smoking to improve wound healing
Ladies if you may be pregnant, please tell your doctor ASAP.
Please have nothing to eat for 6 hours and nothing to drink for 2 hours before any procedure.
Please take your normal medications with a sip of water.
Please obtain specific instructions, if you are taking strong analgesics, warfarin, clopidodrel, insulin or diabetic tablets.
Please start weaning your pain killers in the 4-6 weeks leading upto your trial, to allow microdosing. Ideally the Morphine equivalent daily doses will be under 20mg for non-cancer pain to get the best long term results with the least side-effects. This is not always possible for cancer related pain and a different approach is taken.

**Procedure:**
You may or may not undergo a trial of the therapy with "active" and "placebo" medications before receiving a permanent implant. Testing will vary with your condition and situation but may include one of the following methods:

1. One to four spinal injections of medication with an overnight hospital stay.
2. The insertion of a temporary spinal catheter and trial of several medications over a one-week hospital stay. If the trial is unsuccessful, the catheter is pulled out.
3. The implantation of a permanent spinal catheter connected by an extension or implanted port to an external pump for an extended trial. Several medications will be trialled over 4-8 weeks. If the trial is successful, a pump will be implanted. If the trial is unsuccessful, the catheter will be removed surgically.
4. The implantation of a permanent spinal catheter and drug pump for a 3-6 month 'ambulatory trial' to allow assessment, titration and optimising of the pump medication. If pain is not controlled, the pump and catheter will need to be removed surgically.

There is no one proven or agreed best method for trialling intrathecal drug therapy in all patients. Your treating physician will determine the best method for you.

**Medications:**
Medications commonly used include inactive placebo (saline), midazolam, clonidine, pethidine, bupivacaine, morphine, hydromorphone, baclofen; combinations may also be tested prior to device implantation. Medication related side effects include numbness, tingles, nausea, vomiting, decreased appetite, constipation, itching, fluid retention, urinary difficulties, dizziness, anxiety, muscle weakness, low blood pressure, hormonal changes, sedation, confusion, breathing problems. Withdrawal effects may occur if morphine-like analgesics are weaned and ceased during the trial.

**Observations:**
For your safety you are closely monitored during the trial and after medication change. Vital signs are recorded every 5 minutes for first 15 minutes, then 15 minutely for 1 hour, half hourly for 4 hours and 4 hourly until medication effect ceases. Pain (or relaxation) symptoms and improvement will be assessed hourly, at rest, with activity and overnight.

**Instructions: Trial/Screening External Pump:**
The intrathecal drug trial using Option 2 or 3 may be continued at home with an external pump to see how you cope with normal activities and determine any side effects.
The following instructions need to be followed for your safety:
1. Check temperature with a thermometer 2-4 times per day. Report any elevation above 38°C.
2. Use ice packs on wounds to reduce swelling, bruising and discomfort for 1-2 days. Report any unexpected redness, inflammation or swelling.
3. Don't get the pump or dressings wet.
4. Sponge baths only - no showers, baths, swimming or soaking.
5. Report to the clinic any severe, persistent nausea, vomiting, severe headache (constant or positional), excessive drowsiness or breathing problems (rate less 8 breaths per minute while awake).
6. Report any profound weakness or numbness occurring after discharge from hospital. Protect and support of the affected area if weakness or paralysis occurs.
7. Diabetic medications and anticoagulants need specific instructions. Resume all routine home medications.
8. Use other pain killers only as directed.
9. Routine activities may be resumed, slowly increase as tolerated. No strenuous activities.
10. **Do not** drive a car or operate machinery or make important decisions within 12h of a new drug.
11. External pumps usually need to be refilled at weekly intervals during trials.

**Instructions: Implanted Pump & Catheter:**
After implantation surgery the pump is programmed and medication adjusted by your pain specialist as needed to control your pain/spasticity. It may take several months of adjustment to obtain the best possible improvement. Please follow your prescribed activity plan and progressively resume your desired activities as tolerated. It is usually safe to return to sedentary work in 2 weeks, more vigorous activities in 4 weeks and most people wanting to work have found and returned to work within 4-6 months.

**The following instructions need to be followed for your safety:**
1. Use ice packs on wounds to reduce swelling, bruising and discomfort for 1-2 days. If your pump has been implanted in the abdomen, wearing bicycle shorts or a corset over the pump may help reduce swelling. Please bring a suitable clothing item when you come into hospital.
2. Check your temperature if wound redness or headache, report any elevation over 38°C
3. Report unexpected wound redness, inflammation or swelling as this may indicate infection.
4. Showers may begin 24hours after implantation – keep wounds dry. No tub baths, swimming or soaking until review.
5. Report to the clinic any severe, persistent nausea, vomiting, severe headache (constant or positional), excessive drowsiness or breathing problems (rate less 8 breaths per minute while awake).
6. Report any profound weakness or numbness occurring after discharge from hospital. Protect and support of the affected area if weakness or paralysis occurs.
7. Diabetic medications and anticoagulants need specific instructions. Resume all routine home medications.
8. Use pain killers only as directed.
9. Routine activities may be resumed, slowly increase as tolerated. No strenuous activities.
10. **Do not** drive a car until comfortable, minimise driving in first 2-3 weeks. Watch position of seat belt.
11. Please make an appointment to see your doctor in 2 weeks or earlier if necessary.
12. Find out when your pump needs to be refilled.
13. The Synchromed pump program needs to be checked ASAP after a MRI scan. Please arrange to have the MRI on days when the pump can be checked in the clinic after the scan.
14. Avoid ultrasound examinations or short wave diathermy within 10cm of the pump.

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# SPINAL DRUG DELIVERY CONSENT/REQUEST

I _____
Given Names Surname

Patient Information, Consent and Request for a spinal drug delivery to control my pain.

I acknowledge that my Doctor has given me and a support person (if desired), the opportunity to ask questions. I confirm that my doctor has provided me with adequate information to make an informed decision:

1. About my medical condition, its consequences, prognosis, chance of recovery, alternate treatments such as strong pain killers, nerve blocks, spinal cord stimulation and surgery.

2. That there is no guarantee that Spinal Drug delivery will improve pain control, quality of life, solve personal or family problems and that sometimes adequate pain relief or muscle relaxation cannot be achieved.

3. About the risks and hazards of continuing with my current treatment, the proposed surgery and anaesthesia.
   4a. I understand that common to all therapeutic and diagnostic procedures is a chance of infection, blood clots in veins and lungs, haemorrhage/bleeding, allergic reactions and death.
   4b. I also aware that the following specific problems may occur: *Worse pain, no pain relief, nerve damage, paralysis, loss of bladder / bowel / sexual function, numbness, postural headache, equipment failure or catheter migration needing revision, meningitis and serious infection that may require system removal.*
   *4c. Medication related side effects may include: nausea, vomiting, loss of appetite, difficulty passing urine, itch, constipation, fluid retention, hormonal changes, sedation, life threatening drug overdose and respiratory depression from programming errors or pump mis-fills. Physical dependence may develop such that withdrawal symptoms may occur with sudden cessation. Tolerance may develop and require alternate drugs or a 'drug holiday' to re-establish pain control (relaxation).*

5. To help me actively manage my own pain, participate if requested in a pain management program, attend all medical and like appointments and comply with reasonable treatment requests.

6. About the known possible problems and the possibility of unknown risks associated with long term spinal drug administration and that my questions have been answered to my satisfaction.

7. I understand that pumps will need refilling periodically, for as long as I wish to continue this treatment.

8. I have read the attached information on spinal catheters, implanted drug delivery systems and discharge instructions.

9. About the possible risk of rare severe complications and potential impact on financial stability (including repayments for loans, mortgage, educational responsibility), the need for ongoing treatment, further interventions or surgery, dependency on family or carers, prolonged recovery in physical and mental health have been discussed.

10. After considering the above information, I consent to and request the insertion of a spinal injection or catheter for a spinal drug trial and if successful implantation of a permanent drug delivery system.

Dated _____ Signed _____

Relationship to patient (if other than self) _____

**Confirmation**

I , _____
(name of doctor)
have explained to the patient / person legally responsible for the patient, the nature and effects of spinal drug delivery. In my opinion, He / she understood this explanation.

Dated this _____ day of _____ 20 ___ Signature of Doctor _____

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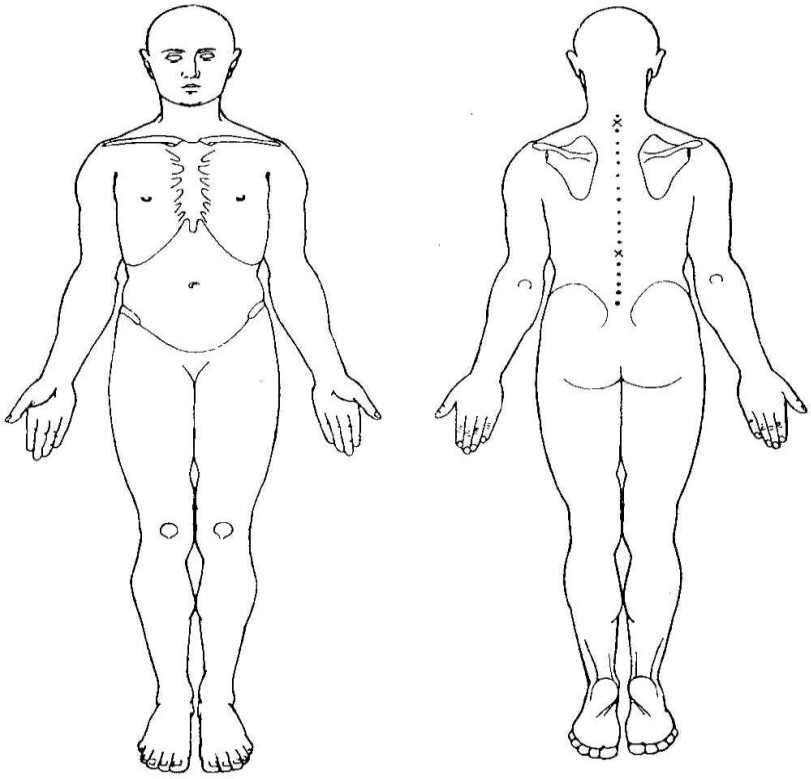
# DAS Trial Record

Patient Name: _____ Date: _____

1 Mark the area on the attached diagram where you usually feel pain



3. During the Trial did you accomplish your goals? (answer yes or no)

| IT Drug | Medications | Goal 1 | Goal 2 | Goal 3 | Goal 4 | Goal 5 |
|---|---|---|---|---|---|---|
| Describe Goals | Analgesic Use | | | | | |
| A | | | | | | |
| B | | | | | | |
| C | | | | | | |
| D | | | | | | |
| E | | | | | | |
| F | | | | | | |

List Medications to be weaned:

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# Discharge Instructions – Diagnostic Intrathecal/Spinal Injections

Patient Name: Date:

Injectate: Level:

Pain Scores

| | Pain at Rest x/10 | Pain with Activity x/10 | | Pain at Rest | Pain with Activity x/10 | Pain at night & ability to sleep |
|---|---|---|---|---|---|---|
| Before | | | Day 1 | | | |
| 30 mins | | | Day 2 | | | |
| 60 mins | | | Day 3 | | | |
| 2 hours | | | Day 4 | | | |
| 3 hours | | | Day 5 | | | |
| 4 hours | | | Day 6 | | | |
| 5 hours | | | Day 7 | | | |
| 6 hours | | | Day 8 | | | |
| 8 hours | | | Day 9 | | | |
| 12 hours | | | Day 10 | | | |
| 18 hours | | | Day 11 | | | |

**Instructions.**

1. Use ice packs on injection site(s) to reduce swelling, bruising and discomfort for 1-2 days.
2. Report any unexpected redness, inflammation or swelling or temperature above 38ºC.
3. Report to the clinic any severe or persistent nausea, vomiting, severe headache (constant or positional), new fluid retention/ankle swelling, excessive drowsiness or breathing problems (rate less 8 breaths per minute).
4. Report any profound weakness or numbness occurring after discharge from hospital.
5. Resume all routine home medications. Use other pain killers only as directed by your pain specialist.
6. Routine activities may be resumed, slowly increase as tolerated.

1. Did you experience any of the following new side effects?

| Drug | Itching | Ankle swelling | Sweating / flushing | Breathing problems | Nausea /Vomit | Headache | Sedation | Urine Difficulty | Numbness Weakness |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |

2. Did you or did you think could accomplish your goals? (answer yes or no)

| Drug | Goal1 | Goal2 | Goal3 | Goal4 | Goal5 |
|---|---|---|---|---|---|
| Describe | | | | | |
| | | | | | |
| | | | | | |

Was the procedure helpful (circle response) YES / NO

How much relief? (0-100% relief) :

Comments:

**Emergency Contact:**

If you have any questions, concerns or problems, call (03) 9770 0522 during office hours. If the problem is urgent attend the nearest Emergency Department.

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# Discharge Instructions – Temporary Catheter & Ambulatory Pump

The drug trial may be continued at home to see how you cope with your normal activities and side effects. The following instructions need to be followed for your safety.

**Epidural, Spinal/Intrathecal Catheter or Pump Side Port Access with External Pump**

1. Check temperature with a thermometer 2-4 times per day. Report any elevation above 38$^{o}$C.
2. Use ice packs on wounds to reduce swelling, bruising and discomfort for 1-2 days. Report any unexpected redness, inflammation or swelling.
3. Report to the clinic any severe, persistent nausea, vomiting, severe headache (constant or positional), excessive drowsiness or breathing problems (rate less 8 breaths per minute).
4. Report any profound weakness or numbness occurring after discharge from hospital. Protect and support of the affected area if weakness or paralysis occurs.
5. Resume all routine home medications. Use other pain killers only as directed by your pain specialist.
6. Don't get the pump or dressings wet for 1 week. Sponge baths only, no showers, baths, swimming or soaking.
7. Resume usual activities, slowly increase as tolerated. No strenuous activities.
7. **Do not** drive a car or operate machinery or make important decisions within 12h of a new drug or dose.
8. Your ambulatory pump will need to be refilled weekly during this trial.

**Rate the severity** of your usual pain and sleep interference using a 0-10 scale, twice-daily with each trial drug.

| Solution | Time | Lying | Sitting | Standing | Walking | Sleeping |
|---|---|---|---|---|---|---|
| Before | | | | | | |
| | Day1-am | | | | | |
| | Day1-pm | | | | | |
| | Day2-am | | | | | |
| | Day2-pm | | | | | |
| | Day3-am | | | | | |
| | Day3-pm | | | | | |
| | Day4-am | | | | | |
| | Day4-pm | | | | | |
| | Day5-am | | | | | |
| | Day5-pm | | | | | |
| | Day6-am | | | | | |
| | Day6-pm | | | | | |
| | Day7-am | | | | | |
| | Day7-pm | | | | | |

3. During the Ambulatory Trial did you experience any of the following new side effects?

| Drug | Itching | Ankle swelling | Sweating / flushing | Breathing problems | Nausea /Vomit | Headache | Sedation | Urine Difficulty | Numbness Weakness |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |

4. During the Trial did you or thought you could accomplish your goals? (answer yes or no)

| Drug | Goal1 | Goal2 | Goal3 | Goal4 | Goal5 |
|---|---|---|---|---|---|
| Describe | | | | | |
| | | | | | |
| | | | | | |

Was the procedure helpful (circle response) YES / NO
How much relief? (0-100% relief) :
Comments:

**Emergency Contact:**
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# Discharge Instructions – Post Insertion Spinal Drug Pump & Catheter

**POST IMPLANTATION:**
After implantation surgery the pump is programmed and medication adjusted by your pain specialist to control your pain/spasticity. It may take several months of adjustment to obtain the best possible pain relief. Please follow your prescribed activity plan and progressively resume your desired activities as tolerated. It is usually safe to return to sedentary work in 2 weeks, more vigorous activities in 4 weeks and most people wanting to work have found and returned to work within 4-6 months.

## The following instructions need to be followed for your safety.

## Implanted Intrathecal Catheter with Internal Pump

1. Use ice packs on wounds to reduce swelling, bruising and discomfort for 1-2 days. If your pump has been implanted in the abdomen, wearing bicycle shorts or a corset over the pump may help reduce swelling. Please bring a suitable item when you come into hospital.
2. Check temperature if wound redness or headache report any elevation over 38$^{o}$C
3. Report unexpected wound redness, inflammation or swelling as this may indicate infection.
4. Report to the clinic any severe, persistent nausea, vomiting, neck stiffness, severe headache (constant or positional), excessive drowsiness or breathing problems (rate less 8 breaths per minute while awake).
5. Report any profound weakness or numbness occurring after discharge from hospital. Protect and support of the affected area if weakness or paralysis occurs.
6. Showers may begin 24hours after implantation – keep wounds dry. No tub baths, swimming or soaking until wound healed.
7. Resume all routine home medications. Use other pain killers only as directed.
8. Routine activities may be resumed, slowly increase as tolerated. No strenuous activities.
9. **Do not** drive a car until comfortable, minimise driving in first 2-3 weeks. Watch position of seat belt.
10. Please make an appointment to see your pain specialist in 2 weeks. Please make an earlier appointment if necessary.
11. Your pump will need to be refilled on: ……...

**In the 3 months since the device was implanted, have you had any of the following side effects?**

| IT Drug | Itching | Ankle swelling | Sweating / flushing | Breathing problems | Nausea /Vomit | Headache | Sedation | Urine Difficulty | Numbness Weakness |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |

**In the 3 months Since the device was implanted have you accomplished your goals? (answer yes or no)**

| Drug | Goal1 | Goal2 | Goal3 | Goal4 | Goal5 |
|---|---|---|---|---|---|
| Describe | | | | | |
| | | | | | |
| | | | | | |

## Emergency Contact:

If you have any questions, concerns or problems, call (03) 9770 0522 during office hours. If the problem is urgent attend the nearest Hospital Emergency Department.