This Information booklet is destined to physicians who need to share basic information about Intrathecal Drug Delivery with their patients. All questions regarding therapy choices should be discussed with a physician.
What is Intrathecal Drug Delivery?

Intrathecal drug delivery, often shortened to IDD, is a special way to deliver pain-relieving medicine. Instead of taking the drugs orally, which affects the whole body, it is applied in a very low dose directly into the intrathecal space, the liquid-filled area around the spinal cord in the column. To achieve this, an implantable device such as a pump is needed.

How does it alleviate pain?

If drugs are taken orally, they are spread by the circulation system throughout the body and only a small part of the initial dose reaches the target pain receptors in the spinal cord. The nerves in the spinal cord transmit the pain signals to the brain, where the signal is transformed to the "feeling" or "sensation" of pain. When pain relieving medicine, such as morphine, is applied directly into the fluid surrounding these nerves, only a small fraction of the oral dose is needed to get the same pain relief. Typically, this leads to fewer of the side effects seen with many medicines taken orally.

Intrathecal Drug Delivery can help:

• Manage pain more effectively
• Improve Quality of Life
• Reduce oral medication and the related side effects

This guide was designed to introduce Intrathecal Drug Delivery. We hope it will answer some of the questions and concerns regarding this technique. We would like to give a basic understanding of the therapy, the device and how it will affects life. A doctor will be able to provide more information and help determine if this therapy is adequate for each case.

For more than 50 years, Medtronic has worked with doctors around the world to create products and therapies that alleviate pain, restore health, and extend life for millions of people around the world. We are now a global leader in medical technology, including site-specific drug delivery for the management of chronic pain.
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1.1 How does it alleviate pain?

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Intrathecal Drug Delivery can help -

- Manage pain more effectively\(^1,2\)
- Improve Quality of Life\(^1,3\)
- Reduce oral medication and the related side effects\(^3\)
When is Intrathecal Drug Delivery (IDD) an option?

In general, IDD is effective for chronic pain of any sort. The following criteria are used to identify whether or not IDD is right for someone with chronic pain:

- Patient suffers with chronic pain, which means they have had constant or recurrent pain for more than 3 months
- More common treatments have failed to adequately relieve the pain and/or caused unacceptable side effects
- There is a disease causing the pain, for example:
  - Intractable Pain
  - Complex Regional Pain Syndrome (CRPS)
  - Failed Back Surgery Syndrome (FBSS) not responding to Spinal Cord Stimulation
  - Phantom Limb Pain
  - Postherpetic Neuralgia
  - Axial Somatic Pain
  - Osteoporosis
  - Cancer Pain
- There is no psychological condition/reason that prevents the success of treatment, including substance addiction
- No other medical problems exist that would prevent the operation

Patients should discuss with their physicians about their specific conditions and the benefits and disadvantages of each pain therapy available.

IDD can control pain with a small fraction of the dose that would otherwise be required with tablets.

1.2 What does the IDD implant consist of?

The IDD system consists of two implanted parts –

1. The first is the Intrathecal catheter, this is a small, soft tube
2. The second is the pump itself, with its reservoir containing pain relieving medicine

Both are placed inside the body during a surgical procedure that in many cases lasts approximately an hour. This procedure is performed under anaesthesia.

- The programmable pump automatically delivers set amounts of the pain relieving medicine
- The doctor can quickly and easily change the dose, rate and timing of medicine delivered by the pump using a small, hand-held programmer, adjusting the medication to individual pain requirements
- The doctor may also recommend a hand-held patient programmer that communicates with the pump via radio waves. In addition to the timed doses (amounts), the patient can request extra doses of medicine, within limits set by the doctor. This is helpful if the patient experiences unpredictable or irregular pain, often known as breakthrough pain.

Once the patient receives his IDD system, the doctor will periodically refill the pump with pain relieving medicine. This is done by inserting a needle through the skin into the pump’s reservoir. The battery on the pump should last an average of 5–7 years, again depending on the dose. When the battery in the pump expires the pump will sound an alarm, at this stage the patient will need a replacement pump. Much like the initial implant, this surgical procedure will be performed under anaesthesia.
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Patients should discuss with their physicians about their specific conditions and the benefits and disadvantages of each pain therapy available.
3 What are the steps for Intrathecal Drug Delivery

3.1 Test

Once the decision has been made to try IDD, a test is usually performed. This allows the patient and his doctor to see how effective IDD may be before deciding whether to have the operation. The test can be done on an outpatient basis or the patient may be admitted for a short hospital stay.

The test allows the patient and his doctor to see how well IDD works before deciding whether to have the operation.

There are two ways to do the test which is usually carried out under local anaesthesia:

- Single injection or several injections: A small amount of pain relieving medicine is injected into the spinal column, similar to an epidural injection.
- Continuous infusion: Pain relieving medicine is delivered continuously to the spine through a small tube. One end of it is placed in the fluid surrounding the spinal cord and the other end is attached to an external pump.

This test lasts several days or weeks and closely resembles the treatment delivered by IDD during daily activities.
3.2 Implant

If the test is successful, and a decision was made to go ahead with IDD, the pump is implanted in an operation that may require a short hospital stay.

- Before the operation, the patient and his surgeon will decide the most comfortable and suitable place for the pump. Usually this position is below the belt-line to one side of the lower abdomen.
- Surgery typically in many cases lasts around 1 hour and is performed under anaesthesia.
- The surgeon will place the pump just below the skin in the area defined above.
- A small skin incision in the back is needed to stabilize the catheter in its position. The catheter is then passed below the skin to the pump and securely connected to it.
- Once the pump and catheter are in place, the incisions are closed and the operation is concluded.

3.3 Post-surgery care

After the surgery, there will be some discomfort and tenderness where the pump and catheter have been implanted. Often antibiotics are prescribed to avoid infections. If any excessive redness, swelling or soreness is noted around any of the wounds the medical team must be notified.

The patients should be advised to restrict their activities for a few weeks after surgery to allow the implanted pump system to “settle”. Once the wounds have healed the pump site requires no special care.

4 Living with IDD Therapy

4.1 Living with an IDD pump

As the patient begins receiving therapy his awareness of the programmable pump will lessen. Since there are no external parts, he may even forget it is there. The patient may find that wearing loose clothing is most comfortable. Depending on the patient size and body type and where the programmable pump is placed, it may not show at all under regular clothes.
4.1.1 Practical issues

When receiving IDD Therapy, it is very important for you to follow the instructions of the medical team. The patient should also:

- Always attend the follow-up and refill appointments
- Immediately notify the medical team if a pump alarm sounds (a beeping noise)
- Carry patient identification and emergency cards with him at all times, detailing the name of the pump system implanted and the drug name and current dosage of the medication
- Tell his other doctors and his dentist about IDD Therapy and the presence of the implanted pump, particularly prior to undergoing any medical procedure
- Make sure his family and friends know about the programmable pump, so that they can provide support when required
- If he plans to travel, inform his medical team so they can make sure enough medicine is in the programmable pump

4.1.2 Physical activities

The patient will be advised to avoid physical activities that could impact the area around the pump or the catheter and activities that greatly affect the temperature or pressure of the pump, such as deep heat therapy or scuba diving.
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4.1.3 Follow-ups and refills

The frequency of follow-up visits varies from weeks to months, depending on the dose of medication required. These visits are necessary to refill the programmable pump and adjust the dosage to best suit the pain requirements. The medical team will establish how often the patient needs to get the programmable pump refilled. During a typical session, the programmable pump will be emptied and refilled by a needle inserted through the skin. Medication might be changed and the pump reprogrammed. It is important to keep all the refill appointments to maintain the level of medication needed for effective therapy. The medical team will also check the pump working status and monitor the battery status at refill appointments to ensure effective therapy.

4.1.4 Magnets

The Pump may be affected by strong magnetic fields, like the ones created by magnetic resonance imaging (MRI), CT-scans, radiation treatment or diathermy. Physicians should always be consulted before having any additional treatments or tests.

4.1.5 Alarms

The pump has alarms that will beep softly to indicate when it should be checked. The alarm will sound when only a limited amount of drug remains in the pump reservoir or when the pump is nearing the end of its battery life. If an alarm sounds, the medical team should be contacted to determine the cause and make any necessary adjustments.
4.1.6 Battery

The SynchroMed® II pump battery lasts up to seven years. The exact battery life depends on how much medicine the pump is programmed to deliver each day. After any consultation or refill the doctor can see what the expected remaining lifespan of the pump battery is. Before the battery runs out, the pump will need to be replaced with a new one, which requires a surgical procedure. The catheter usually can stay in place and be reconnected to the new pump.

4.1.7 myPTM

The physician may prescribe a myPTM – Personal Therapy Manager – this device gives the possibility of self-administering additional doses of medication when the patients experience pain peaks (breakthrough pain). This provides an additional possibility to control pain effectively.
4.2 What are some of the risks of the pump therapy?

4.2.1 Surgical, hardware and therapy complication

Problems with IDD are rare but it is important to be aware of them so that they can be corrected as soon as possible. As the pump and catheter are put in place during an operation, normal surgical risks apply, and complications such as infections are possible. Other potential complications include bleeding, pain and discomfort, and blood or fluid in the pump's pocket; in rare occasions, inflammatory mass have formed around the tip of the catheter. The catheter could become dislodged or blocked, or in rare cases, the pump could stop working. This would cause a reduction in or loss of pain relief and may need an operation to resolve the issue, but is extremely rare.

4.2.2 Drug Side Effects

Drug side effects are possible even with the low doses that are applied with IDD. The possible side effects depend on the type and dose of drugs prescribed. The patients should discuss with their doctor about the medication chosen and its potential side effects. It is also important for caregivers and family members to be aware of the first signs and symptoms of overdose or withdrawal in order to be able to alert the medical team, if necessary. Patients may ask their physicians for information about these potential risks and the recommended actions.
Q. What happens if the pump runs out of medicine?
A. If the pump reservoir runs empty the pain will return and the patient may experience withdrawal symptoms. Their doctor can tell when the pump will run out by checking it with the programmer during regular check ups. He or she will make a refill appointment before the pump runs out of medicine. The pump has an alarm to let the patient know when it is time for a refill. It will emit a soft high-pitched beeping sound repeated several times per minute. It is important to try and have the pump refilled before the alarm sounds. When the alarm sounds, the doctor should be called for an immediate refill appointment.

Q. Will the pump prevent the patient from travelling?
A. Flying in commercial airlines will not generally affect the pump. It is always advisable to inform the medical team prior to any long flights or flights in any non-pressurized aircraft for any recommendations. If traveling on holiday it is important to ensure that the pump contains enough medication for the holiday duration.

Q. Will the patient be able to take hot baths or showers?
A. Most of the time, a hot bath, shower or sauna will not interfere with the pump’s operation. After the surgery incisions are healed, a hot bath that is less than 39 °C does not affect the pump. At higher temperatures, the pressure in the pump reservoir increases. If the increase is significant, the pressure can cause the pump to deliver too much medication. The patient should talk to his doctor about other activities that may greatly affect the temperature or pressure of the pump, such as deep heat therapy or scuba diving.

Q. What safety precautions should the patient follow with the pump?
A. The patient can safely use most common household appliances including microwave ovens, televisions, radios, remote controls and video games. But the pump can be affected by magnets. For this reason the patient should avoid magnets. These, depending on strength, could affect the pump. In addition, various medical activities and equipment may affect the pump. These include magnetic resonance imaging (MRI), radiation treatment and diathermy. Patients should always consult their doctor before having any additional treatments or tests.

Q. Are there any special instructions for patients receiving the pump?
A. Patients should avoid physical activities that might damage the pump site. It is essential that they keep all follow-up appointments as scheduled.

Q. In which occasions is intrathecal drug delivery (IDD) an option?
A. A doctor will perform a test to see if IDD works before deciding whether to have the operation. The test can be done as an outpatient or the patient may be admitted for a short hospital stay. Testing can be done in two ways. It can either be one injection or several injections of a small amount of pain relieving medicine into the intrathecal space. Or, the patient can have a continuous injection of pain relieving medicine through a temporary tube placed in the intrathecal space and attached to an external pump. The patient may have to stay in the hospital or he may return home with the external pump for several days or weeks. The doctor will also carry out a psychological assessment. As chronic pain involves both mind and body, it is very important to see if there are any psychological aspects of the pain that need to be treated.

Q. How does intrathecal medicine differ from oral medicine?
A. IDD delivers medicine directly to the spinal cord, where pain signals are transmitted. In contrast, medicines taken by mouth affect the whole body. This often causes side effects such as sleepiness and confusion, which may stop doctors from giving greater amounts of pain relieving medicine this way.

Q. Can a patient stop taking other pain medicines when he receives his pump?
A. His doctor will assess whether he still need to take other medicines. Many patients find that IDD leads to a reduction in the need for pain relieving medicines. To prevent any negative side effects, patients should not make any changes unless their doctor has told them to do so.

Q. What risks are associated with IDD?
A. Complications are rare, and are only seen in a very small number of patients. As the pump is put in place during an operation, problems such as infections are possible. A rare complication involves the formation of an inflammatory mass around the tip of the catheter. The catheter could move or become blocked. In rare cases the pump could stop working. This would cause a reduction in, or loss of, pain relief and may require another operation to correct, but is extremely rare. Patients should talk to their doctor about the possible side effects of IDD.
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A. Patients should avoid physical activities that might damage the pump site. It is essential that they keep all follow-up appointments as scheduled.
Q. Will the pump cure the pain?
A. No. This therapy provides pain relief but does not cure the reasons why the patient has the pain.

Q. Will the pump be noticeable?
A. The dimensions of the pump are 8.75 cm in diameter and either 1.95 cm or 2.6 cm in thickness. Dependent on the implant technique of the surgeon, the choice of reservoir size of the SynchroMed® II pump, and the size of the patient, the pump may or may not be noticeable as a small bulge of the skin in the lower abdomen. The pump is usually implanted below the “belt-line”, which combined with loose clothing makes it unlikely that anyone other than the patient will be aware of the implant.

Q. What is the pump made of?
A. The pump is made of titanium - metal deliberately chosen to minimise the potential of an allergic reaction. In addition, the catheter is made of silicone, also to reduce the risk of an allergic reaction.

Q. Can the patient have a scan once implanted?
A. Patient with an implanted SynchroMed® II pump can safely have an X-ray. Although the pump is made of titanium, an implanted patient can also have a CT or MRI scan observing special precautions. The physician can obtain these precautions from Medtronic prior to the exam.

Q. How will the patient know when the pump needs to be replaced?
A. The battery contained within the pump will last up to 7 years. During routine visits to the medical team they will be able to monitor the battery life of the pump using the physician programmer device. They will be able to actively schedule a pump replacement before the existing battery expires. The pump also has an alarm which will sound when the battery reaches “end of life” status.
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References
3. Ilias, le Polain, Buchser, Demartini the oPTiMa study group (2008), Patient-Controlled Analgesia in Chronic Pain Patients: Experience with a New Device Designed to be Used with Implanted Programable Pumps, Pain Practice, Volume 8, Issue 3, 2008 164–170

Please refer to the product technical manuals and the appropriate drug labeling for a listing of the indications, contraindications, warnings, precautions and adverse events.