



THE BRITISH PAIN SOCIETY

Intrathecal drug delivery systems for treating pain and spasticity

Information for patients

Prepared on behalf of the British Pain Society
in consultation with the Association for Palliative Medicine and
the Society of British Neurological Surgeons.

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Intrathecal drug delivery systems for treating pain and spasms

Information for patients

Your hospital specialist team thinks that you might benefit from having an intrathecal drug delivery (ITDD) system. This system is often just called a 'pump'.

This booklet tells you about ITDD systems. It gives you some of the information that you might need before you can decide whether this might be right for you.

Living with chronic pain or spasms

You have almost certainly been in pain or have been suffering from spasms for a long time.

We know that being in pain for a long time changes the way that people live their lives and the way they feel about themselves. It is common to experience all sorts of complicated feelings such as frustration, anger, worry or a sense of helplessness and despair.

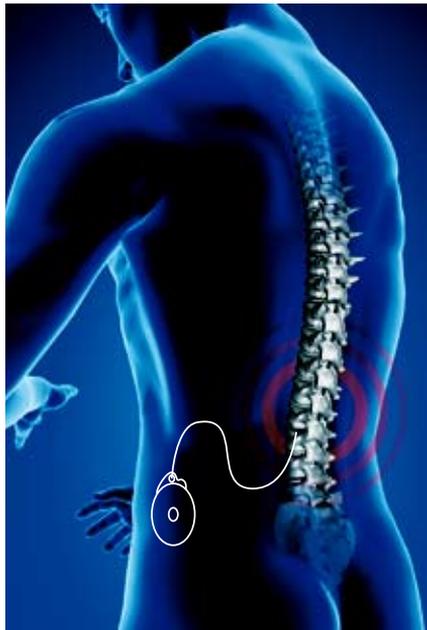
Why might a pump help me?

Many people with persistent pain or muscle spasm take regular medication to help relieve their symptoms. Over time, some people find that they do not get as much benefit from the medication or that the side effects become unbearable.

A pump delivers medication directly to special areas in the space containing the spinal fluid (intrathecal space). Because of this, you need much lower doses of medication as the drug does not have to travel around the body first. This usually results in greater benefits and decreased side effects.

A pump is not a cure and may not get rid of all of your pain or spasm. You may still have to take other medicines. However, it can be a better way to control your symptoms than your current drugs and may mean you can become more active, return to more of your everyday activities and enjoy better sleep. There are three parts to an ITDD system.

- 1 **The actual pump**, a small battery-powered device which is implanted in the abdominal area.
- 2 A thin, flexible tube (**catheter**) which is connected to the pump and implanted in the intrathecal space



Position of catheter and pump when implanted

- 3 **An external programmer** which is used by your doctor or nurse to communicate with and programme your pump during your refill and check-up sessions.

The pump is filled with a drug that is released at a set rate, through the catheter, into the intrathecal space.

How effective is ITDD?

Your specialist will decide whether they think a pump may benefit you. Ask your specialist what their results are for people with your particular condition.

Even if you get good pain relief from your pump, it will only be one part of the overall plan to manage your pain.

Will I need to travel to a specialist centre for ITDD?

Generally, ITDD is only available at specialist centres which have a lot of experience using this technique and have enough staff to offer patients care whenever they need it.

This may mean that you have to be prepared to travel some distance to a suitable centre. You need to consider whether you are willing and able to travel when you are in pain. You will also need to decide whether you will be able to afford the travel costs of the journey. Remember that you will have to make regular visits for pump refills.

Will my usual doctor know how to adjust my medication?

The specialist team will adjust your medication and let your GP know about the change. Your GP can contact a member of the team if they need to find out more about the medication you have been given.

How does the screening process work?

ITDD does not work for everyone or every condition. If your specialist thinks it might help you, a screening process, also known as a 'trial', will be carried out before you and your doctors consider a permanent pump. This allows you and your specialist team to decide how well the system will work to reduce your pain or muscle spasm.

Before the trial, there will be a thorough assessment of your pain and its effect on you and your day-to-day life.

What happens during the trial?

For the trial, you will have to go to hospital. While you are there, the medical team will insert a tube into your intrathecal space under local anaesthetic. The tube comes out through the skin. The team will give various drugs to you through the tube at different times, and decide how useful these are to you. You will not normally know which drugs you are having. When the trial is finished, the tube will be removed. If your trial is successful and you get good pain relief, you and your doctors may decide that you should go on to have a permanent implant.

How is the permanent pump inserted?

If you have the permanent pump, you will have to go to hospital. The operation is done under general or spinal (numbing from the waist down) anaesthetic. The surgery involves implanting the pump into a small pocket of skin on your abdomen. This is connected to the catheter that is inserted into the intrathecal space of your spine.

After surgery you may experience some discomfort around the area where you have the implant which can be treated with simple painkillers. This usually settles over the next few days and it is important to become more active because this will help you to recover more quickly.

The pump is filled and programmed while you are still in hospital. This is done by the specialist staff at the hospital using the external programmer that can communicate with your pump to make these changes.

Implanting the pump takes a few days' stay in hospital and once comfortable on the drugs that have been found to suit you, you will be allowed home. You may have clips to close the wound and these will be taken out after seven days. You should gradually increase your activity over this time, and you will be reviewed by the team. At the time of the review your pump will be refilled.

It is very important that you get 24-hour contact numbers before you leave hospital in case you have any problems with the implant.

During the first few days or weeks after surgery, the dose of drug in the pump may need to be adjusted to give you the best results.

Your pump will need to be refilled and checked regularly.

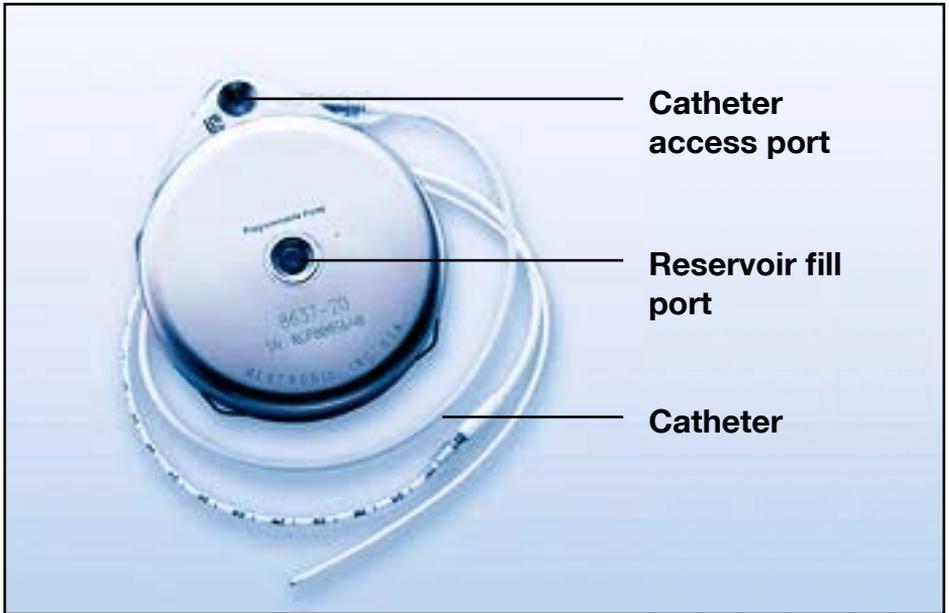
The pump can hold either 18 millilitres (mls) or 20mls of drug and will set off an alarm if the reservoir (supply of drug in the pump) falls below 2mls. The alarm makes a small audible bleeping sound. Your pump will usually be refilled before this alarm goes off.

To get the best possible pain relief, it is vital that you make regular visits to the centre where you had the implant for follow-up care.

This usually means that you will need to have a follow-up visit roughly every three to six months, depending on the type of pump you have, and how much medication you need. The refill date will be checked during your follow-up appointments. When you have follow-up sessions, the pump is usually emptied and refilled

by a sterile injection through the skin on your abdomen. This is a relatively easy and painless procedure. If necessary, the team can adjust your dosage in these sessions.

This visit will take about one hour and you can drive yourself home if you want.



Pump and catheter

It is very important that you keep to your appointments.

You will need to get the pump refilled before it runs out, to manage your pain or spasms effectively.

How long does the pump last?

The pump is powered by a small internal battery. This can last between three and seven years, depending on the type of pump. If the battery needs to be changed, you will need to stay in hospital and you will usually need an anaesthetic.

What are the risks and possible complications of a pump?

As with any procedure, there are some possible risks and complications.

It is common for patients who undergo the trial to experience back pain where the catheter is inserted. This is not a serious complication and usually only lasts a few days. Some people also suffer from headaches, again lasting a few days.

During the trial and after the pump is installed, there can be side effects from the drug that is being infused such as nausea and vomiting, itching and problems passing urine. All these problems can be easily treated.

Some side-effects of the drug can be potentially serious, such as breathing problems and sedation. During the trial and in the first few days after the pump has been inserted, the team will monitor you closely so that they can treat any side-effects quickly.

Complications such as spinal fluid leaks, infection, meningitis, abscesses, bruising and damage to the spinal cord, scar tissue formation, catheter problems or pump malfunction can happen but they are very rare.

When your pump is refilled there is a risk that the drugs could be given wrongly, but this is also very rare.

How will I know when a refill is due?

At the time of each refill you will be given an appointment that falls one to two weeks before the date your pump is due to alarm. If your pump needs to be refilled before this scheduled appointment, you may hear the pump alarm or find your pain or spasm is not being as well controlled.

How often does the pump have to be refilled?

This will depend on the type of pump you have and how quickly the drug is released. However, this is likely to be about every three to six months.

How long does the refill take?

This can vary but usually takes about 30 to 45 minutes.

What happens if my pump runs out of medication?

What happens if the pump stops can vary depending on the type of medicine you are using. The effect, if you stop taking some of the drugs suddenly, can be very serious. You should discuss with your doctor what the effects would be if the pump ran out of medication, and what you should do if this happens. It is important that you keep to your refill appointments to stop the pump running out of medication. The pump can be seriously damaged if the medication runs out.

What do I need to do when I go home?

It is important that when you go home, you keep your wounds dry and clean until they have healed and the stitches or staples have been removed. You should also look out for any signs of infection such as redness, swelling or leaking around your wounds.

How long will it take me to recover?

You will be able to carry out:

- occasional light lifting three weeks after surgery;
- work and driving four to six weeks after surgery; and
- heavy lifting, twelve weeks after surgery.

These timescales are only a guide and may vary for different people.

How soon will I start to feel benefit from the ITDD?

You may not notice the benefit of having the ITDD system for several weeks. Your doctor may reduce your pain or spasm medication over this time.

If I may not notice the benefit for several weeks, what use is the trial?

During the trial, doctors will use higher doses of drugs than you would normally need. They may give you them in a dose that works quickly, rather than over a long period of time. This means your body responds more quickly, meaning the doctor will be able to find out sooner whether it will help you.

What if my pain relief does not improve after the ITDD is implanted?

You should let your doctor know. They may change the dose or type of medication used in the pump.

Can I stop taking other medicines if I have the pump?

You may be able to, but you should follow the advice of your doctor.

Can I take hot baths, showers or go on sun beds?

You should take care in very hot baths or on sun beds. Discuss this with your doctor or nurse.

Will people be able to see that I have a pump?

People may be able to see the swelling over the area where the pump is implanted.

Will it affect what clothes I can wear in terms of comfort or possible discomfort? If so, how?

The pump is placed where it is least likely to get in the way of belts and waistbands. Tight clothing may make the pump visible. Someone will discuss this with you before the procedure.

Will I be uncomfortable or at risk wearing a seat belt?

When the specialist team decide where to place the pump, they will consider your comfort . So far no risk of using a seatbelt has been identified.

Can I fly and scuba dive?

As long as you do not go higher than 7000 feet above sea level, or more than 78 feet under water you should not have any problems with your pump. Most standard and long haul flights will not affect your pump. Your nurse or physiotherapist can discuss any effects with you.

When can I return to sport?

You can start walking again when you feel well enough and start swimming when your wounds have healed. You should gradually build back up to other sports over the following six to eight weeks. If you feel the pump moving it is advisable to wear something tight to limit this. Your physiotherapist or nurse will give you more information about this. You should avoid contact sports such as rugby as they could cause the catheter to move out of the correct position. If your catheter becomes dislodged after a fall or a blow, you will probably find that your pain is controlled less effectively, you might notice swelling or fluid where the pump was installed in your

body, and start to feel generally unwell. If this happens you should contact the team as soon as possible, or the ward if it happens out of working hours.

Technical questions about ITDD

What happens when my battery runs out?

When the pump battery needs to be replaced you will need to stay in hospital for a short period. This will generally involve an anaesthetic.

Is there an alarm to show there is a problem with the pump?

There are alarms which warn you that the drug level is low, that the battery is low or that there is a problem with the pump. These alarms vary from device to device. Your doctor and nurse will discuss with you what the alarms sound like and what they mean before you leave hospital with the pump in.

If I hear the alarm, how long do I have before the battery runs out?

Your pump should be refilled before the alarm goes off. If you hear the low-battery alarm, you should arrange to have your battery replaced immediately.

Will electrical equipment interfere with the pump?

Most electrical equipment such as mobile phones, microwaves and household tools will not interfere with the pump. However some large industrial equipment may have an effect. Because of this, you should avoid getting too close to industrial welding equipment, or equipment that creates a strong electromagnetic field. Certain treatments can also interfere with your pump, such as short-wave diathermy (heating deep tissue using electricity), radiotherapy, therapeutic ultrasound and bone-growth stimulators. Because of this, it is important that you let your dentist and physiotherapist know that you have a pump. Standard x-rays will not interfere

with the pump but MRI scans may. If you need an MRI scan, tell the radiologist that you have a pump before you go to your appointment.

Will security devices interfere with the pump?

Theft or security devices will not affect how well your pump work. However, the metal in the pump may cause certain security devices to set off an alarm, for example those found in airports, shops and libraries. Because of this, it is important to carry your ID card with you in case this happens. (This will be given to you by the hospital when you have the pump put in.)

Can the catheter become dislodged or tear?

The catheter can be dislodged or tear if you move suddenly or vigorously. You should take care if you exercise or move quickly. You can discuss this with your doctor or nurse.

The working party

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Competing interests

Members of the group have declared their competing interests (financial connections with companies that are involved in intrathecal drug delivery systems, that might influence advice) as follows.

Doctor Kate Grady

Has no competing interests.

Ms Sue Clayton

Has no competing interests.

Mr Paul R Eldridge

- implants devices manufactured by Medtronic (a company which produces treatments for chronic pain);
- has been performing research on using ITDD to Baclofen to improve spinal cord stimulus funded by Medtronic; and
- is a member of Medtronic Advisory board (and receives payment for this).

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