Intrathecal Drug Delivery for Spasms and Chronic Pain

Intrathecal drug delivery systems are implanted pumps that target pain relief or anti-spasm medication to an area of the spine that relays signals between an affected area of the body and the brain.

Persons with chronic pain or muscle spasms may be considered for such a device if, over time, the medications they have been taking have become less effective, or the side effects more difficult to tolerate. Although receiving an implanted pump is not a cure, it may allow patients more symptom relief, participation in daily activities, and better rest.

With these systems, medication is immediately released into the fluid surrounding the spinal cord and directly reaches the nerves in the spinal cord that are responsible for symptoms, such as perception of pain.

For this reason, much lower amounts of the active ingredient, such as morphine, are needed than when medication is taken by tablet or intravenous infusion. Compared to medication taken by mouth, an intrathecal pump usually only requires 1% of the dose.

Not only is direct delivery more effective, it also avoids, to a large degree, overall side effects throughout the body that occur with medication taken by mouth or injected into the bloodstream through intravenous infusion.

The Implantation of the Infusion Pump

For this therapy, the doctor places a catheter beneath the skin and into the space along the spine (the intrathecal space) to release the medicine into the cerebrospinal fluid that bathes that area.

In this way, the drug reaches the part of the body that relays nerve signals quickly and exerts its effect directly, without involving digestion (for medications taken by mouth) or the bloodstream (for injected ones).

During an initial trial, while the patient stays at the hospital, medication is delivered through this catheter for a time period of one to three weeks, while the dose is gradually increased until an effective dosage level is found.

If the effect is satisfactory, the next step is to implant the infusion pump. The pump is implanted under the skin, usually in the upper abdomen, in a sort of "pocket" between skin and muscle tissue. The patient will need to be cautious about movements that may affect the placement of the implant.
Implantation takes roughly one hour. The patient often will be temporarily “asleep” under general anesthesia during the procedure, although using local anesthesia to numb the area instead is also quite common.

The length of hospital stay depends on the individual case, and any other measures that may also be taken at this time.

For targeted (intrathecal) drug infusion, there are two systems:

**Fixed-rate pumps**

Fixed-rate pumps operate mechanically and are powered by a gas pressure chamber surrounding a flexible inner reservoir, both made of titanium. There are small-scale and larger-scale drug reservoir options in order to minimize refilling while keeping overall dimensions as compact as possible.

Gas in the pressure chamber is warmed by body heat and expands, squeezing the inner chamber to drive the drug through a filter and so-called choke line, then on through the catheter to the site of action in the body.

The device incorporates microsystems engineering for a compact design, and includes a throttle to precisely deliver a highly accurate flow rate.

Depending on treatment needs, the dose of pain medication is adjusted to individual needs, making the device operation simple and safe.

Changes in pressure or temperature have very little influence on the flow rate, ensuring the device remains highly accurate under different conditions.

The pump is designed for long life. The purely mechanical drive operates without a battery.

**Variable-rate pumps**

Variable-rate pumps include a drug reservoir from which they automatically dispense a programmed amount of medication through a catheter. These pumps have a small, on-board battery and integrated microelectronic circuits to control the drug delivery.

Your doctor may adjust the amount and timing of drug delivery quickly and easily with a small computer-like programmer, which includes such parameters as:

- Current date and time
- Patient identification
- Drug name, concentration and dose
- Infusion mode
- Reservoir volume and setting, when a signal will sound at low level
- Alarm (audible) when the battery is low
**Infusion Mode**

The infusion mode determines the dose, schedule and duration in which medication is administered.

The implanting physician will work with a patient’s primary care doctor to adjust and monitor an overall medical regime, including any prescription medications used in addition to the intrathecal drug.

**Adjusting to Life with an Intrathecal Drug Delivery System**

A patient may truly begin to notice reduced symptoms after several weeks. In follow-up visits, medication dose or type may be adjusted as needed.

Patients may notice a slight visible swelling over where the pump is placed although the implant is positioned where it should be least likely to get in the way of belts and waistbands. Care should be taken when exercising to not move quickly or engage in sports that might cause components to become dislodged or the catheter to tear. If a tear occurs, the patient may start to realize the pain is more noticeable, the implant area has swelling or fluid, and he or she is beginning to feel generally unwell. If an accidental tear or dislodgement is suspected, it is important to seek care as soon as possible.

Security gates do not interfere with the device, although its metal may set off the security system. Patients are given a card to show if this occurs at security gates, for example those found in airports, shops and libraries.

Pressure changes from either commercial air travel in cabins pressurized to 7,000 feet or undersea dives down to 78 feet should not pose problems. However, it is best to avoid going near large industrial equipment that creates a strong electromagnetic field, such as welding equipment, since it may affect device programming.

Certain treatments can also interfere with the pump, such as short-wave diathermy (heating deep tissue using electricity), radiotherapy, therapeutic ultrasound and bone-growth stimulators, so it is important to notify providers in advance about the implant. Standard X-rays will not interfere with the system, but MRI scans may, so radiologists should also be told prior to an appointment.

**Refills and Replacements**

Refills are generally done every three to six months, using a sterile needle inserted through the skin of the abdomen. Pumps hold 18 or 20 milliliters and will signal with a beeping noise if the amount gets below 2 milliliters. The devices also sound alarms if there is a malfunction, or, for versions with a battery, if the battery runs low (generally between three to seven years of use). When the battery runs low, the implant will be replaced under anesthesia.
Risks and Possible Complications

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, which can all 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 a patient 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 are very rare.

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

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