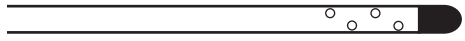
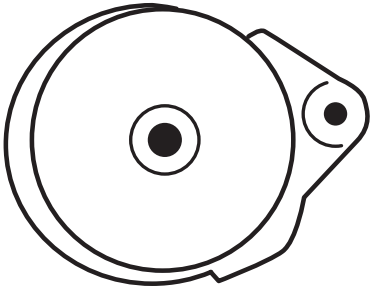
PROMETRA® II

PATIENT GUIDE

For use with Prometra® II Programmable Pump System





FLOWONIX

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Glossary

Abdomen: soft space between your ribs and hip bones

Arachnoid: the middle protective membrane covering the brain and spinal cord

Anesthesia: medicine that causes you to lose your ability to sense pain, among other sensations

Bolus: large or concentrated dose of medicine

Cardioversion: electrical "jump start" for your heart to correct irregular rhythms. Also may be done with medication(s).

Catheter: tiny flexible tube

CSF: cerebrospinal fluid

Chronic: long-term

Contrast media: dye that can be seen under x-ray

CT: non-invasive, non-magnetic scan used to verify intrathecal catheter position

DEHP: Bis(2-ethylhexyl)phthalate, a plasticizer in PVC

Defibrillation: stopping the heart from quivering, "fibrillating", instead of pumping normally. Often done by applying electricity via small paddles but may also be done with medication(s).

Dura Mater (Dura): the outermost protective membrane covering the brain and spinal cord

Epidural: located outside the dura mater, or anesthesia injected into this space.

Explant: to take out; opposite of implant

FDA: US Food and Drug Administration

Granuloma: Inflammatory mass

Hyperbaric: pressures higher than normal atmospheric pressure

Implant: to put in

Intractable: difficult-to-manage; hard to treat, relieve, or cure

Intrathecal space: fluid-filled area around the spinal cord

Latex: natural rubber

Orally: by mouth

Palpable: that which can be felt by touching

PVC: polyvinyl chloride, a plastic material

Programmable: ability to be controlled remotely

Prometra: brand name for Flowonix Medical's programmable drug delivery pump and pump system

Saline: Salt water balanced to match your body's composition

Telemetry: remote transmission of data

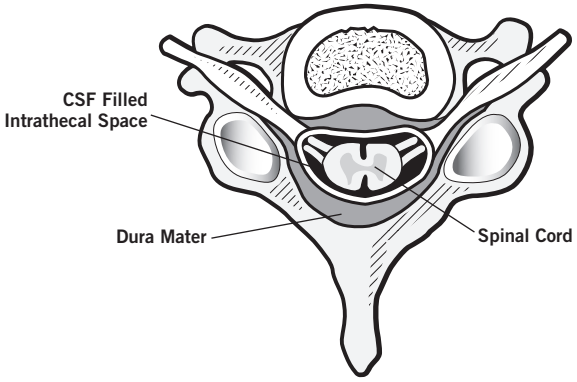
Vertebra/Vertebral Body: bones or segments which make up the spinal column and through which the spinal cord runs

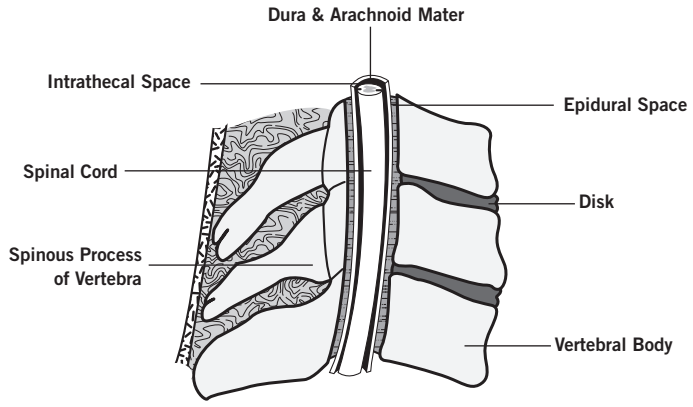
Descriptive Information

Your doctor is recommending this treatment for you because your prior treatments have not been adequate to control your symptoms. This Patient Guide will help you understand your Prometra II Programmable Pump System and answer your questions about this treatment. However, it is only a guide and **your doctor and nurse are always your best source of information**. Be sure to ask them to explain anything that is unclear. And, always follow their directions concerning your Prometra II Programmable Pump System.

Potential Benefits of the Prometra II Programmable Pump System

Your spinal cord is the main pathway for information connecting your brain and all the rest of the nerves in your body. If you take a pill orally (by mouth), medicine has a much harder time reaching the spinal cord as much of the drug is absorbed by your body along the way. Delivering this dose directly to your spinal cord reduces the amount of medication needed to control your symptoms. For example, published studies show that you can take 1/100th of your medication when it is delivered to your intrathecal space (fluid-filled space around your spinal cord) and achieve the same symptom relief. With a much smaller intrathecal dosage, your side effects may be reduced. Or, your doctor may be able to increase your dosage without as many side effects.





Descriptive Information

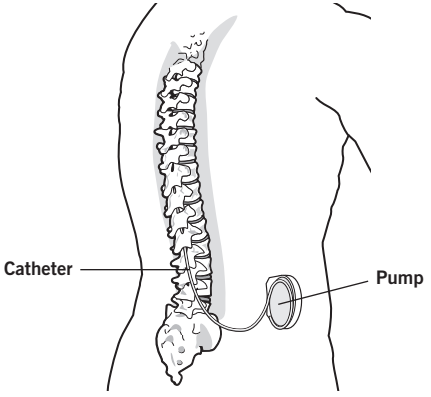
Purpose of the device (approved indications for use)

Your Prometra II Programmable Pump System is approved to infuse preservative-free morphine sulfate directly into the intrathecal space to relieve chronic (long-term), intractable (difficult-to-manage) pain or baclofen sterile injection for treatment of severe spasticity. Sterile preservative-free saline (salt water) solution or intrathecal contrast media (dye that can be seen under x-ray) may also be used in your pump. Your doctor may decide to put other medications in your pump other than morphine or baclofen. This is at your doctor's discretion, as other medications have not been approved for use with the Prometra II Programmable Pump System.

Please read the drug label for additional information. The National Library of Medicine at **www.nlm.nih.com** is a good source for drug information.

Description of the device

The **Prometra II Programmable Pump System** provides drugs directly to your spinal cord. The Prometra II pump and its intrathecal catheter are Latex-free, PVC-free and DEHP-free.

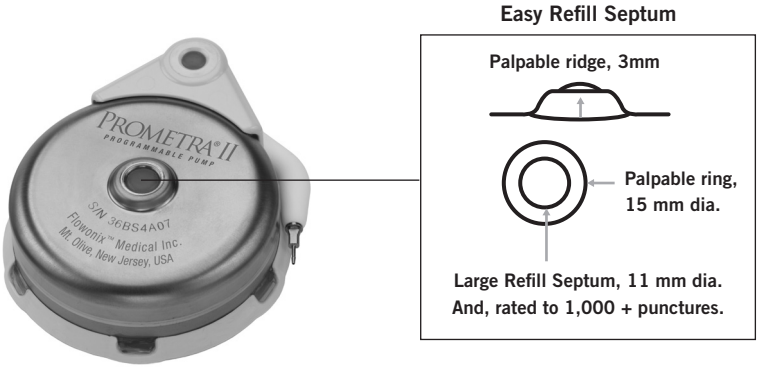


Descriptive Information

Description of the device

A tiny **intrathecal catheter** with holes near the end is carefully placed in your intrathecal space and securely connected to the Prometra II programmable pump implanted in your abdomen (the soft space between your ribs and hip bones). Your catheter has a radiopaque tip that can be seen under x-ray.

The pump has a central refill septum that a nurse or doctor can feel underneath your skin (palpate). Your medicine will be refilled every 30-60 days by accessing this refill port with a thin needle. If needed, the nurse or doctor may access your catheter directly to provide a bolus (large or concentrated dose) of medicine through the catheter access septum.



When you initially receive the pump, and at most refills, the nurse or doctor will use a handheld programmer, like a remote control, to set how much medicine to deliver and at what times. Your programmable pump can deliver different amounts of medication at different times of the day, such as more at night while you are sleeping and less during the day.

Descriptive Information

Description of the device

Prometra Programmer

Making the Decision if the Pump is Right for You

The pump system should not be implanted: Contraindications

- When you have an infection, such as a tooth abscess or a bed sore.
- If your body type cannot comfortably or safely accommodate the pump size and weight.
- If the pump cannot be implanted under your skin 2.5 cm (1 in.) deep.
- With spinal column anatomy that would obstruct cerebrospinal fluid flow or prevent intrathecal drug delivery.
- If you work or live near high current industrial equipment, transmitting towers, or powerful magnets.
- If you need hyperbaric treatments.
- If you have allergies to the catheter materials, including silicone rubber, acetal resin, or tungsten.
- If you have allergies to the pump materials, including silicone rubber, polyphenylsulfone, buna-n (nitrile) rubber, MP35N metal (multiphase quaternary nimonic alloy primarily composed of chromium, cobalt, molybdenum and nickel), titanium, polyvinylidene fluoride, stainless steel, epoxy resin, acetal resin or tungsten.
- If you are deemed an unsuitable candidate after psychological evaluation.
- If you are under 22 years old. Safety and effectiveness for use in pediatric patients under 22 years old is unknown.
- If you have any contraindication to preservative-free morphine sulfate or baclofen as per the approved drug labeling. The National Library of Medicine at www.nlm.nih.com is a good source for drug information.

Descriptive Information

Making the Decision if the Pump is Right for You

After Your Pump is Implanted: Warnings and Precautions

Avoid applied electric currents

Interaction of the Prometra II Programmable Pump System with electric currents applied to the body, such as cardioversion or defibrillation, has not been established. In non-emergency situations, the pump should be turned off before application of electric currents. Your doctor will need to confirm that the pump programming has not changed must be carried out as soon as possible after the procedure.

Avoid powerful magnets, such as MRI

During an MRI procedure, your pump may stop delivering drug. Your doctor may arrange for alternate means of drug delivery (such as I.V. administration) while you undergo the MRI procedure. After your MRI procedure, your doctor must perform a reset procedure to return the pump to its programmed flow rate.

Testing has demonstrated that the Prometra II Pump can be safely exposed to specific MR systems when certain **critical** conditions are applied. Your doctor will need to understand and adhere to these critical conditions prior to any exposure to an MRI environment.

Avoid transmitting towers, large electrical antennae and in-use welding equipment

Exposure could result in pump malfunction. Please discuss your local environment and occupation, or potential occupation, with your implanting or pump management doctor.

Do not use radiation therapy in the area of the pump

The effects of ionizing radiation on the Prometra II Programmable Pump System have not been established, and these therapies may have effects on pump operation that are not immediately obvious.

Risks

The Prometra II Programmable Pump System provides an important means of treating patients with intractable pain and severe spasticity. However, there are potential side effects and complications that you should understand. Also, since your pump and catheter are placed during a surgical procedure, surgical complications may occur. Always discuss the potential risks and benefits of this therapy with your doctor and ask any questions that you have.

Lastly, since the Prometra II Programmable Pump System may remain implanted for ten (10) or more years, take time to familiarize yourself thoroughly with the therapy and take an active role in your outcome.

Descriptive Information

Making the Decision if the Pump is Right for You

Risks

Potential complications may include:

- Accumulation of clear fluid, bleeding, infection, and inflammation near the surgical sites. If you notice redness, swelling or pain at the implant site or have a fever, call your doctor immediately. Infections occur in 5-10% of patients and are typically treated with antibiotics.
- Battery depletion or pump failure causing lack of medication delivery. This occurs in 1% of patients and would require pump removal.
- Catheter breakage, blockage, disconnection, kinking, and movement. If you notice an increase in symptoms, contact your doctor at once. This occurs in 15% of patients and may require reoperation to reposition or replace the catheter.
- Erosion of catheter or pump through the skin. This is extremely rare, and has not occurred with the Prometra II pump.
- Flipped pump causing inability to perform refills. This occurs mainly as a result of "fiddling" with the pump. This occurs in 1% of patients. This may be able to be re-flipped without surgery or it may require surgery.
- Inability to program the device due to programmer failure or loss of telemetry. This occurred in none of our study patients, but it is still possible. If it is permanent, the pump will need to be removed and replaced.
- Inflammatory mass (granuloma) or scarring near the catheter. This is uncommon, occurring with similar devices in less than 2% of patients. It usually occurs years after your initial surgery. You need to tell your doctor immediately about any new neurological signs or symptoms, including:
  - Burning, numbness, or tingling
  - Increase in pain despite dose escalation
  - Increased sensitivity to stimuli or pain
  - Progressive change in the type or amount of pain
- Pain on injection. If this is different from prior refills, it may be an early sign of infection. Please refer to infection information above.
- Programming or refill errors resulting in under-dosing or over-dosing. Errors occur due to miscalculations by medical staff less than 3% of the time.
- Rejection of the material in the catheter or pump requiring possible removal of the implants. This is extremely rare, occurring in less than 0.5% of patients.
- Reoperation. Reoperation before normal battery failure occurs in 15% of patients mostly due to infection or catheter movement.

Descriptive Information

Making the Decision if the Pump is Right for You

Risks

- Scarring externally or internally at the pump and catheter surgical sites. Everyone has a different tendency to scar more or less, and it varies based on a large number of factors. Your doctor is the best person to ask about this.
- Spinal cord injury or pressure or nerve injury causing impaired movement, partial loss of movement, or paralysis. This is an infrequent complication, occurring in 2% of patients. Surgery is typically required to either replace or remove the pump and catheter.
- Spinal fluid leak causing headaches or ringing in the ears. This occurs in 7% of patients. The leak may resolve by itself and did so in all of our study patients. If it does not, a reoperation may be required to close the leakage.
- Other risks associated with surgery and general or local anesthesia. Your doctor can best advise you about your particular risks based on your individual history.
- Reopening of previously closed wound. This occurs in 3% of patients and typically requires reoperation with local anesthesia to repair.

Potential Side Effects of Morphine

- If nausea occurs, consult your doctor or pharmacist for ways to decrease it (such as taking antihistamines, lying down for 1 to 2 hours with as little head movement as possible).
- This medication may cause dependence, especially if it has been used regularly for a long time or in high doses. In such cases, withdrawal reactions (such as restlessness, watery eyes, widened pupils, sweating, runny nose) may occur if you suddenly stop this drug. To prevent withdrawal reactions, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details, and report any withdrawal reactions immediately.
- When this medication is used for a long time, it may not work as well. Your doctor may need to increase your dose or change your medication. Talk with your doctor if this medication stops working well.
- Along with its benefits, this medication may rarely cause abnormal drug-seeking behavior (addiction). This risk may be increased if you have abused alcohol or drugs in the past. Use this medication exactly as prescribed to lessen the risk of addiction.
- Tell your doctor if your pain persists or worsens.
- Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, increased sweating, or dry mouth may occur. Pain, redness, or swelling at the injection site may occur if this medication is given into a muscle or under the skin. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.
- To prevent constipation, maintain a diet adequate in fiber, drink plenty of water, and exercise. Consult your pharmacist for help in selecting a laxative (such as a stimulant type with stool softener).
- Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Descriptive Information

Making the Decision if the Pump is Right for You

Potential Side Effects of Morphine

- Tell your doctor immediately if any of these unlikely but serious side effects occur: slow/shallow breathing, fainting, mental/mood changes (such as agitation, hallucinations, confusion), difficulty urinating, vision changes, slow/fast heartbeat.
- Tell your doctor immediately if any of these rare but very serious side effects occur: severe stomach/abdominal pain, change in the amount of urine, seizures.
- A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.
- This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

Potential Side Effects of Baclofen

Careful attention to the programming and monitoring of the pump is required to prevent some of the risks and problems associated with baclofen. To decrease these risks you must go to regular follow-up visits and always follow your study doctor's instructions.

Potential side effects with baclofen include:

- The drug not being effective in managing your symptoms
- Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.
- Sweating, diarrhea, constipation, rash, emotional problems, abnormal thoughts and sudden change in personality, headache, dizziness, seizures, stroke, slow or fast breathing, pneumonia, pulmonary embolus (a blood clot in the lung), sudden decrease or increase in blood pressure, slow or fast heart rate, palpitations, abnormal heart rhythm, urine retention, kidney failure, increased muscle tone, decreased muscle tone. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.
- This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

Serious Side Effects of Baclofen

Serious Side Effects can occur due to an over-dose, under-dose, or sudden stoppage of baclofen delivery. **Seek emergency medical attention immediately if signs of under/overdose appear:**

- Early symptoms of **under-dosing or withdrawal** of baclofen can be return to baseline spasticity, itchy skin, low blood pressure, and generalized "pins and needles" in your skin.
- Signs of overdosing can be drowsiness, lightheadedness, dizziness, slow or difficult breathing, seizures, and loss of consciousness that could lead to a coma.
- **Abrupt withdrawal of baclofen may be life-threatening.** Signs of a sudden stop of baclofen flow (or "abrupt withdrawal") into your spine can be: high fever, change in mental status (this might include confusion, amnesia, poor judgment, drastic mood changes), and sudden increase in spasticity. If you do not receive medical treatment, the sudden stop of baclofen flow could result in breakdown of muscle tissue, multiple organ failure, and death.

Descriptive Information

Making the Decision if the Pump is Right for You

Benefits

Implantation of the Prometra II programmable pump system is usually used when conventional pain treatment is no longer effective. Benefits you can expect include:

- Improved symptom relief
- Less need for oral medications
- Less side effects due to the reduced intrathecal dosage
- More functionality and daily activities

Before, During and After Your Procedure

Your Pump Implant Surgery

The Prometra II Programmable Pump System will be placed in your body during a surgical procedure that is usually about 1 hour long. You will be given anesthesia which will allow you to sleep through the surgical procedure without pain. Your doctor will give you specific instructions about how to prepare for the surgery.

Both the pump and catheter are implanted under your skin. A small incision is made in your back to provide access to your spinal canal. The tip of the catheter is threaded up your spine into your intrathecal space while using a form of x-ray. Your doctor usually places the pump at about waist level (abdomen), above your hip bone and below your ribs, and to one side. The catheter is tunneled underneath your skin from where it enters your spine around your waist to the pump. The catheter length is then customized to your body and connected to the pump. Your doctor may chose to use sutures near where the catheter enters your spine. This will help the catheter to maintain its position.

Your pump will be filled and programmed to deliver your medication at either a constant or variable rate, or it can be set to give a dosage repeated at specified times. Your doctor will determine the best medication schedule for you.

When you wake up, you will notice two incisions. Your doctor made one incision in your abdomen to place the pump. Another small incision is made in your back to position the catheter in your spine.

Follow-up Visits

Your first follow-up visit will be scheduled one to two weeks after surgery. At this visit, your doctor will look at the surgical site and review the medication therapy plan that was started when you received your pump.

Descriptive Information

Before, During and After Your Procedure

Refills

Your doctor will schedule regular pump refill visits as needed so that your pump does not run out of medication. This is usually about every 30-60 days. Only your doctor or nurse can program your pump to deliver medication. **It is important NOT to miss a refill appointment.** You should always let your doctor know as soon as possible if you think you will miss an appointment. This will allow time for a new appointment to be set or for other arrangements to be made. **If your pump is not refilled on time, it may become empty, and you will not get your required medicine. When you run out of medicine, your symptoms can range from fairly minor to very serious depending on the medicine you were receiving, such as with baclofen, serious risks can occur due to a sudden stop in drug delivery.** Your doctor can describe the symptoms to expect if your pump runs out of medication or if you stop getting medicine from the pump for any reason.

To refill your pump, your doctor will insert a special needle of just the right size and length into your pump through the center refill septum. For most patients this causes only a mild pricking sensation. Then, your doctor or nurse will completely empty your pump. Your pump must be emptied to measure the amount of medication that was left in the pump. This allows verification that the pump has been delivering the right amount of medicine to your spinal cord. Your doctor will then refill your pump by attaching a syringe and tubing set filled with your medication to the special needle and pushing the medication into the pump reservoir. Then, your doctor or nurse will program the pump to deliver your medication using the programmer. Once the pump is refilled and programmed by your doctor, the pump will automatically deliver the medication at the programmed dosage rate.

What should I expect after surgery?

After surgery you may have some redness and tenderness in the area where your incision was made. This will normally go away in a few weeks. However, contact your doctor or nurse if you notice unusual changes in the skin area over the pump such as increased swelling, redness, or soreness.

For the first few days after you receive the pump, you should avoid heavy exertion and strenuous activities such as lifting or pushing, carrying anything heavy, running, and swimming. Follow all your doctor's instructions about your pump. Once your incision heals, you should be able to resume normal daily activities such as bathing and exercising.

Descriptive Information

Before, During and After Your Procedure

Will I need to wear a bandage over the pump?

A bandage will be required until your incision heals. After a refill visit, a bandage may be used over the area where the needle was inserted.

Will others know that I have a pump?

After your incision heals, the pump will likely protrude slightly from your abdomen. In thinner people, it tends to protrude more and in larger people, it is less obvious. Your doctor may be able to provide pictures of what the pump looks like in different body types.

Do I have to wear certain types of clothing?

This depends on where your pump is placed. You should avoid clothing that would rub or be tight over the incision site immediately after surgery. Wear loose, comfortable clothing the day of your implant surgery. After the incisions heal, you should be able to wear your normal clothing.

Can I move my pump, e.g. if it is uncomfortable?

Your pump has been placed with the refill septum facing up so it can communicate with the programmer in your doctor's office. Never move, twist or turn your pump. This may flip your pump or cause damage to the catheter. Either of these may interfere with delivery of your medication or require reoperation. However, typical movement should not result in damage to the catheter or pump.

How do I know if my pump still works after I bump it or if I fall? What about my catheter?

A slight bump is unlikely to affect your pump or catheter. However, if you hurt yourself when you fell, you may have hurt the pump or catheter. If you experience a significant increase in symptoms or notice unusual symptoms, contact your doctor immediately. To verify if your pump and catheter are working, your doctor or nurse will check the amount of medication left in the pump. If too much is left, they may perform an x-ray or CT to verify proper catheter and pump position.

Will my pump set off metal detectors? Is security "wanding" safe?

It may. And, as some personnel are not familiar with the implant card with which you will be provided, you may be asked to show them the pump site. Please consider this when dressing for court appointments, air flights and other facilities where metal detectors might be encountered. If you need to be "wanded" by security personnel, e.g. at the airport, the pump programming will not be affected.

Descriptive Information

Before, During and After Your Procedure

What should I do if I hear my pump beeping or making noise?

Your Prometra II programmable pump has two alarms. Both alarms use the same beeping tone but have a different beep length and different number of beeps in a group. Contact your doctor immediately if you hear these alarms.

The **Low Reservoir Alarm** warns you when the medication in the pump reservoir gets below a certain volume. Your doctor can set this volume, and the alarm can be turned on using the programmer. If the alarm is on and the reservoir volume gets low, the pump sounds two short beeps every 30 minutes. The alarm continues to sound until your doctor turns it off using the programmer or refills your pump.

The **Critical Error Alarm** indicates that the pump has *stopped* delivering medication. The pump sounds three long beeps every 30 minutes. This alarm occurs any time the pump is not delivering medication, including a low pump battery. Once the **Critical Error Alarm** has occurred, the pump stops pumping medication. Your doctor cannot turn off the alarm with the programmer. Your pump will keep beeping until it is replaced or until the battery runs completely out of power. There is no way to replace the battery only. The pump must be disconnected from the catheter and replaced. A new pump can be implanted and connected to the original catheter. Contact your doctor as soon as possible to schedule pump replacement surgery or to assess therapy alternatives.

Will the use of cell phones, a microwave oven, or other household electrical devices interfere with my pump?

No. Your pump is designed so that cell phones, microwaves, or other household appliances and items that you may use in your normal daily life will not affect it. If you suspect interference with your pump, move away from or turn off the electrical device. Your pump will not be permanently affected.

Do pressure changes affect my pump?

The Prometra II programmable pump has a special design which isolates the drug reservoir from most pressure changes, making it **immune to most pressure changes.** You are free to enjoy, with your doctor's permission:

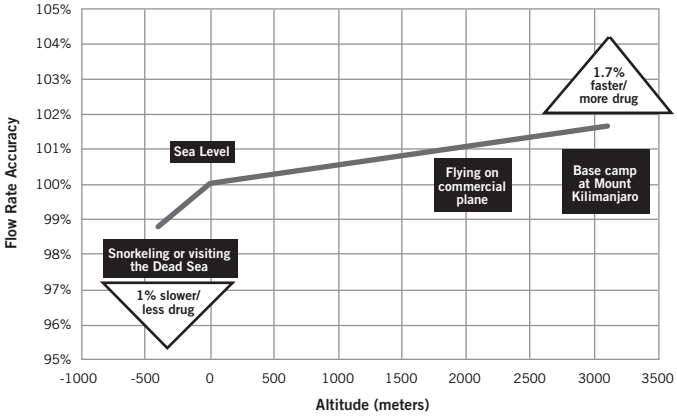
- Flying
- Mountain hikes up to 10,000 feet
- Skiing up to 10,000 feet
- Snorkeling within 15 feet of the surface
- Swimming within 15 feet of the surface

These activities are SAFE and WILL NOT AFFECT YOUR PUMP. Always consult your doctor first about any other activities not listed here.

Descriptive Information

Before, During and After Your Procedure

Do pressure changes affect my pump?



Altitude vs. Flow Rate Accuracy

Activities such as scuba diving or hyperbaric therapy may cause the pump to temporarily stop delivering drug. When you return to normal atmospheric pressure, your pump will resume its programmed drug delivery. Discuss these activities with your doctor to see if you can safely be without your drug during scuba diving or hyperbaric therapy.

Do temperature changes affect my pump?

The Prometra II programmable pump has a special design which isolates the drug reservoir from most temperature changes, making it **immune to most temperature changes**. You are free to enjoy, with your doctor's permission:

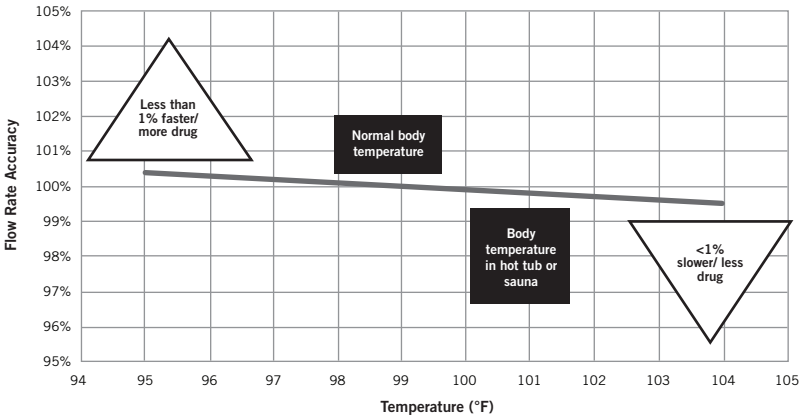
- Hot tubs
- Whirlpool baths
- Saunas

These activities are SAFE and WILL NOT AFFECT YOUR PUMP. Always consult your doctor first about any other therapies not listed here.

Descriptive Information

Before, During and After Your Procedure

Do temperature changes affect my pump?



Temperature vs. Flow Rate Accuracy

Even temperature-related therapies such as deep heat therapy, e.g. diathermy, will not affect the operation of the pump. Always consult your doctor first about any other activities not listed here.

Can I travel with my pump?

The Prometra II programmable pump provides you with the freedom to travel. Let your doctor know if you plan to travel so that pump refill arrangements can be made, if necessary. Also, your doctor can advise you of a doctor in the area you are traveling to in case you have any problems.

What should I do if I move?

Contact your doctor to ask for help finding a new pump management physician who can perform your refills. Then, when you have your new address, please contact Flowonix Medical so we can update our database in case we need to contact you.

Who do I need to tell about my pump and catheter implant?

You need to tell all medical personnel about your implant. This includes doctors, nurses and medical technicians, such as MRI or X-ray technicians. Knowing about the implant may change their treatment or how they conduct or interpret a medical test. To make this easy for you, you will receive an implant card that contains important information about your Prometra II programmable pump and intrathecal catheter. Your implant card should be carried with you at all times.

Descriptive Information

Before, During and After Your Procedure

What do I do if I have a question or suspect a problem?

If it is an emergency, always call 112. If you have pain, fever, chills, shortness of breath, dizziness, or other side effects, contact your doctor immediately. Also, if your pain or spasticity increases or worsens, contact your doctor immediately. If you have any questions or suspect a problem, please contact your implanting or pump management doctor immediately.

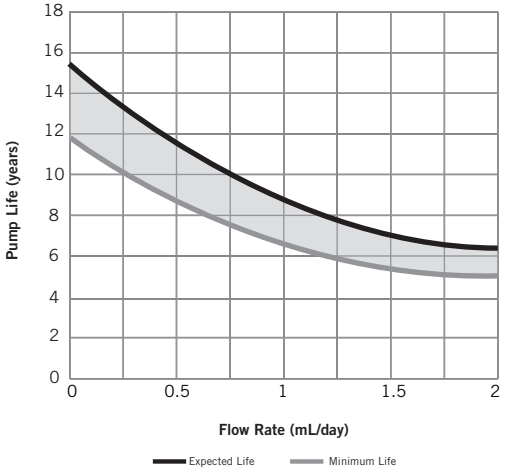
Clinical Studies

In the first clinical study, 110 patients were implanted. Clinical data has been collected on the majority of patients over 12 months. Overall, accuracy of dose delivery was 97%, which is highly accurate. Patients achieved a reduction in pain which was sustained over 12 months. Past the initial 10 days post-implant when medication is being adjusted, there were no reported overdoses, underdoses or withdrawal symptoms noted.

Operating Information

Expected failure time and mode

The Prometra II programmable pump has a battery which powers the pump. The normal battery life of the pump is 10 years at a drug delivery rate of 0.25 mL/day. If you receive a higher flow rate, your battery life may be less. If you receive a lower flow rate, your pump battery should last longer. The chart below will give you an idea of your pump life. If you have any questions, please ask your implanting or pump management doctor.



Prometra Pump Life vs. Flow Rate (0-2 mLday)

Operating Information

Expected failure time and mode

The only way you can monitor the activity of your Prometra II programmable pump system is by keeping track of how well your symptoms are controlled. Please keep a diary or other daily record of your levels, noting your activities immediately preceding an increase or decrease in symptoms. Set aside time to regularly discuss your symptom record with your doctor or refill nurse. Taking an active role in your care will help you to achieve the best symptom control.

Instructions on how to safely dispose of the device

The pump can be removed by your doctor in a surgical procedure like the one that was used to put the pump into your body. Once your pump is explanted, it will be returned to Flowonix Medical for proper disposal.

The pump will need to be explanted upon your death. If you are terminally ill, please notify your caregiver and primary doctor that the pump will explode during cremation and needs to be removed prior to cremation or burial.

Additional Information

Warranty

Flowonix Medical, Inc. (“Flowonix”) warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase, and liability under this limited product warranty will be limited to repairing or replacing the defective product, at Flowonix’s sole discretion, or refunding the net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL FLOWONIX BE LIABLE TO YOU FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, or incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

Travel or international use

There are no restrictions on travel. However, you will want to arrange with your doctor in advance to obtain the name of a local pump management doctor in case of emergency or prolonged vacation requiring a refill.

Date of Printing

Contact Flowonix Medical for a new patient guide when this guide is two years from date listed on last page of this document.

User Assistance Information

Please contact us with any questions or comments either via phone, email or the web. We always welcome patient input.

- customercare@flowonix.com
- www.flowonix.com

If you wish to write to us, we would love to hear from you. Here is our address:
Flowonix Medical Inc.
500 International Drive, Suite 200
Mount Olive, NJ 07828 USA
T 973.426.9229
F 973.426.0035

Rx Only

FLOWONIX

www.flowonix.com

Manufactured by:
Flowonix Medical Inc.
500 International Drive, Suite 200
Mount Olive, NJ 07828 USA
T +1.973.426.9229
F +1.973.426.0035

EC REP **EMERGO EUROPE**
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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