

## Brief Statement for US Health Care Professionals

### IMPORTANT SAFETY INFORMATION FOR PROMETRA DRUG DELIVERY SYSTEMS - BRIEF STATEMENT

Product technical manuals and the appropriate drug labeling must be reviewed prior to use for detailed disclosure. Clinicians implanting, programming, accessing, or maintaining implanted programmable pumps must comply with the instructions for use.

#### Indications:

The Prometra® Programmable Infusion Pump System is indicated for intrathecal infusion of drug therapy, including: Infumorph® (preservative free morphine sulfate sterile solution), preservative-free sterile 0.9% saline solution (Sodium Chloride Injection, USP), and baclofen (baclofen injection, intrathecal, 500-2000 mcg/mL). For Infumorph, the pump is indicated for use in patient populations of 22 years and older (adults). For baclofen and 0.9% saline solution, the pump system is indicated for use in patient populations of 12 years and older (adolescents and adults).

Drug Information: See drug labeling for indications, contraindications, warnings, precautions, dosage, administration, screening procedures and under/over dose symptoms and management. Patients should be informed of signs and symptoms that require medical attention.

Contraindications: Implantation is contraindicated in the presence of infection (known or suspected); insufficient body size or anatomy; incompatible spinal anatomy or obstruction of CSF flow; implant depth >2.5cm below skin; allergies to catheter or pump materials; intolerance to implanted devices; medical history of substance abuse deemed to prohibit intrathecal drug administration; occupations with exposure to high current industrial equipment, powerful magnets or transmitting towers; hyperbaric exposure.

Warnings: FAILURE TO EMPTY THE PUMP PRIOR TO EXPOSURE TO MRI ENVIRONMENT COULD RESULT IN DRUG OVERDOSE THAT COULD LEAD TO SERIOUS PATIENT INJURY OR DEATH; THE PUMP MAY NEED TO HAVE AS MUCH AS 20ML OR 40ML OF DRUG REMOVED DEPENDING ON THE PUMP TYPE AND MODEL NUMBER. USE OF UNAPPROVED DRUGS (e.g., DRUG COCKTAILS, PHARMACY COMPOUNDED DRUGS, MORPHINE WITH PRESERVATIVES, ETC.) WITH THE PROMETRA II PUMP COULD RESULT IN PUMP FAILURE AND/OR SERIOUS ADVERSE EVENTS SUCH AS SEVERE UNDERDOSE, OVERDOSE OR DEATH; Prometra System is MRI Conditional-consult the labeling for MRI information. Medical personnel should be familiar with approved drug intended for use with the implanted pump system, including dosing and symptoms related to and treatment for under- or overdosing.

Precautions: All product instructions should be read prior to use. An inflammatory mass resulting in serious neurological impairment, including paralysis, may occur at tip of catheter. Monitor patients carefully for new neurological signs or symptoms. Monitor patients after pump and/or catheter implant or replacement for signs of underdose/overdose. Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion. Abrupt withdrawal of intrathecal baclofen may be life-threatening. Electromagnetic interference may interfere with Programmer telemetry during pump programming. Pain on injection may be early sign of infection. In the pediatric population, care must be taken to select an appropriate location, taking into consideration available body mass, presence of ostomies, growth development, and comorbidities.

Adverse Events: The potential exists for serious complications. Adverse events include but are not limited to: pocket seroma/hematoma with or without infection, pump site skin erosion, pump rotation/migration/flipping or twisting, adverse reaction to pump materials, granuloma; infection in intrathecal space, including meningitis, nerve damage.

For full prescribing information and full disclosure of contraindications, warnings, precautions, adverse events and MRI Instructions, please call Infusyn at 855-356-9665 and/or consult Infusyn website at [Infusyn.com](http://Infusyn.com)

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.