PROMETRA® II

TECHNICAL COMPARISON

Specification	Prometra® II (40 mL)[1]	SynchroMed® II (40 mL)[2]
General Parameters		
Thickness (nominal)	31 mm	26 mm
Diameter (excluding CAP)	69 mm	87.5 mm
Weight, unfilled	154 grams	175 grams
Volume Displacement	133 mL	121 mL
Device Longevity	10 years @ 0.25 mL/day	4-7 years @ 0.25 mL/day
Material	Titanium	Titanium
Suture Method	360° Plastic suture ring w/silicone suture paths	Metal suture loops
Distance from Refill Septum to Catheter Access Port	4.4 cm (center to center)	4.4 cm (center to center)
MRI	Conditional	Conditional
Flow Rates		
Flow Range	0.0 - 28.8 mL/day	0.048 - 24.0 mL/day
Time to perform ½ mL bolus	25 minutes	30 minutes
Flow Accuracy	± 3% from programmed flow rate	± 14.5% - 19.5% from programmed flow rate
Number of Flow Rates	5 (including Zero-Rate Technology™ and PTC® bolus)	4 (including myPTM™ bolus)
Minimum Flow Rates	0.0 mL/day	0.048 mL/day
Leak Rate in a Stopped Pump	0.0 mL/day	0.030 mL/day
Drug Reservoir		
Reservoir Volume	40 mL	40 mL
Refill Septum		
Average Septum Puncture Life	1000 punctures	500 punctures
Palpable Diameter	15 mm	None
Septum Diameter	8 mm	6.8 mm
Palpable Height	3 mm	None
Access Needle	Huber Point, 22 gauge non-coring (1.5 inches)	Huber Point, 22 gauge non-coring (1.5 inch and 2.0 inches)
Septum Material	Silicone	Silicone

PROMETRA® II

TECHNICAL COMPARISON

Specification	Prometra® II (40 mL)[1]	SynchroMed® II (40 mL)[2]
Catheter Access Port		
Access Needle	Lancet Point, 20 gauge needle (1.75 inches)	24 gauge or 25 gauge needle (1.5 inch or 2.0 inches)
Septum Material	Silicone	Silicone
Delivery System		
Pump Design	Pressure-driven, valve-gated system	Pressure-driven, peristaltic system
Dispensing Mechanism	Dosing chamber surrounded by electronic valves	Three rollers, motor, and ball bearings
Drug Delivery	High volume, high-velocity microliter boluses	Continuous flow
Catheter and Pump Connection		
Pump-Catheter Connection	Sutureless connection & redundant lock	Sutureless connection
Pump-Stem	Flexible silicone arm (90° flexibility)	Rigid titanium (no flexibility)

Specification	Prometra® II[1]	Ascenda™ Model 8780[3]
Catheter		
Total Length	110 cm	86.4 cm
Body Material	Radiopaque, silicone	Radiolucent, silicone
Catheter Tip	Closed tungsten tip with 8 side holes	Closed with 6 side holes
Outer Diameter	1.3 mm (4.0 French)	1.2 mm (4 French)
Inner Diameter	0.6 mm	0.5 mm
Catheter Volume	0.0026 mL/cm	0.0022 mL/cm
Introducer Needle	15 gauge Tuohy	16 T-gauge
Needle Length (cm)	8.9 cm	9.3 cm
Numeric Markings	1 cm interval; between 5 - 31 cm	1 cm; between 12 - 81 cm

1 Flowonix Medical. (2019). Prometra Intrathecal Catheter REF11823, PL-21610-01. http://www.flowonix.com/sites/default/files/pl-21610-01_-_prometra_infusion_systems_intrathecal_catheter_ifu_us_commercial.pdf
2 Medtronic. (2011). Synchromed II Implant Manual (8637) M221211A034: http://www.neuromodulation.ch/sites/default/files/pictures/synchromed_II_implant_manuel.pdf
3 Medtronic Ascenda Intrathecal Catheter with an 86.4 cm spinal segment (2011) IFU. http://manuals.medtronic.com/content/dam/emanuals/neuro/CONTRIB_247043.pdf

Brief Statement for US Health Care Providers
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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). The pump is indicated for use in adult populations of 22 years and older.
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; insufficient body size; 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.
Precautions: 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.
Adverse Events: 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 Flowonix at 855-356-9665 and/or consult Flowonix website at Flowonix.com
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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