

## Implantable Intrathecal Drug Pump Achieves Over Six Years Longevity

The Associated Press

Flowonix Medical has announced that initial patients implanted during the clinical study with the Prometra implantable intrathecal drug pump have reached over six years of device longevity. The Prometra pump is projected to provide a minimum of 10 years of service, with projected longevity of about 13 years at flow rate settings of 0.25 mL per day or lower. This is the longest service life reported of any implantable intrathecal drug pump available today.

"Implantable device longevity is a very important feature in today's healthcare environment," stated Steven Adler, CEO of Flowonix Medical, Inc. "When the pump's battery is depleted, the patient must undergo a surgical procedure to replace it. The longer the pump lasts, the fewer surgeries the patient may have to undergo. That translates into good news for patients and efficiencies for our healthcare system."

Implantable intrathecal drug pumps deliver small amounts of medication directly to the intrathecal space around the spinal column. Patients who require long-term continuous drug therapy may benefit because the pump may reduce the amount of drugs they require for ongoing therapy. Thousands of people with severe chronic pain syndromes have benefited from implantable drug pumps

"The importance of this clinical milestone to physicians who rely on implantable intrathecal drug pumps for their chronic pain patients should not be overlooked," said Dan Kloster, MD, interventional pain specialist in Kansas City, Missouri. "Implantable drug pumps have been and will continue to be a crucial therapeutic option for certain chronic pain patients. Patients who live day in and day out with severe chronic pain depend on these devices for their quality of life. A longer-lasting drug pump is a welcome addition to the market."

Chronic pain affects about around 20% to 30% of Americans and its prevalence increases with advancing age. The World Health Organization has called chronic pain a global epidemic. Untreated or under-treated chronic pain can lead to disability, depression, and reduced quality of life. The Prometra pump is specifically indicated for delivery of Infumorph, a commonly prescribed agent for chronic pain.

The extended longevity offered by the Prometra pump derives from its patented dual-valve gated drug delivery system, which reduces the number of moving parts and allows greater energy efficiencies, which, in turn, enable a long service life. The dual-valve gated system also makes the Prometra pump the most accurate implantable pump in terms of dose delivery to the intrathecal space.

All implantable intrathecal drug pumps must be periodically refilled with medication. The refill port of the Prometra pump offers a unique high-pressure design, providing

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immediate feedback to the clinician during the refill. In the U.S. clinical study, 2,390 pump refills were conducted with the Prometra pump, and none of them resulted in "pocket fills," a potentially life-threatening condition where medication goes into the pocket around the device rather than into the pump. Pocket fills have occurred with other systems.

"This six-year milestone is particularly gratifying, coming after the recent U.S. market approval of the Prometra pump," concluded Steve Adler. "Physicians today have a choice in implantable pumps and with its high degree of accuracy and positive-pressure refill port, Prometra offers unparalleled features. However, our long device service life may be one of the most relevant features for our patients, our physicians, and our nation's healthcare system."

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