FLOWONIX

URGENT: MEDICAL DEVICE CORRECTION

Prometra® II Programmable Pump

May 22, 2017

Dear Healthcare Professional:

Flowonix Medical, Inc. (Flowonix) has received a report of a patient implanted with the Prometra® II Programmable Pump (Prometra II pump) who may have received a fatal drug overdose during an MRI procedure. The Prometra II pump has an FDA-approved design feature intended to permit safe exposure to an MRI without removing drug from the reservoir. The cause of this reported incident is still under investigation.

As a precaution to protect patients, due to this report, **the Prometra II pump labeling has been revised to require that all drug be removed from the pump prior to an MRI procedure.** A copy of the revised Pre- and Post-MRI Instructions is attached to this notification. We are alerting physicians, MRI facilities and patients to this labeling change.

The following Prometra II pump labeling is also being revised, although this process may take several weeks:

Prometra® II Programmable Pump IFU (REF 13827): PL-31790-02
Intrathecal Catheter IFU (REF 11823): PL-22790-02
Catheter Revision Kit IFU (REF 11830): PL-21798-02
Refill Kit IFU (REF 11825): PL-21794-00
Prometra® II Patient Implant Card (Permanent): PL-32300-01
Prometra® II Patient Implant Card (Temporary): PL-32375-01
Prometra® II Patient Guide: PL-31912-01

FDA has been alerted to this field action.

Please acknowledge receipt of this notification by completing and faxing or e-mailing back the attached Response Form.

Please contact your Flowonix Representative or Flowonix Customer Care (855-356-9665) if you have questions or concerns.

Sincerely,

Karen E. Matis

Karen E. Matis, RAC, CCRA
Senior Vice President
Clinical, Quality and Regulatory Affairs
Flowonix Medical, Inc.

Enclosures:
Prometra and Prometra II Pump MRI Scan Instructions PL-15200-00
Response Form PL-15065-00