FLOWONIX

URGENT: MEDICAL DEVICE CORRECTION

Prometra® II Programmable Pump

May 22, 2017

Dear Patient:

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.**

FDA has been alerted to this field action. Flowonix has also notified your physician about this Medical Device Correction. It is important that patients take an active role in understanding that prior to an MRI procedure, the drug in your Prometra or Prometra II pump must be removed.

Flowonix will be sending to you a new Patient Identification Card and a Medical Device Alert Bracelet with the new MRI instruction, along with a revised Patient Guide. Please keep your new Patient Identification Card with you at all times, and wear the new Medical Device Alert Bracelet, thus ensuring that the personnel at any medical facility will be alerted to the presence of the implanted device and the need to remove all drug from the pump before an MRI.

Please contact your physician or Flowonix Technical Support (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.