FLOWONIX

URGENT: MEDICAL DEVICE CORRECTION

Prometra® II Programmable Pump

May 22, 2017

Dear MRI Technicians and MRI Safety Staff:

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.

FDA has been alerted to this field action.

Please assure that any patients who receive an MRI at your facility and are implanted with a Prometra or Prometra II pump have the drug removed prior to the MRI procedure.

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