FLOWONIX

Urgent Field Safety Notice

Product:	**Prometra® Programmable Pump (REF 91827)**
Identifier :	**FSCA-2016-01**
	BSI 07/2016/01-Rev 2- Follow Up Report
Type of action:	**Labeling Change to Update MRI Warnings**

Date: September 20, 2016

Dear Healthcare Professional:

Details on Affected Devices:
Prometra® Programmable Pump (REF 91827) distributed in the European Union
Prometra® Programmable Pump Instructions for Use, New Version: PL-91790-07, effective September 2016.

Description of the Problem and Corrective Action:
Flowonix Medical has become aware of instances where patients implanted with the Prometra Programmable Pump (REF 91827) have undergone MRI procedures without following the labelled MR Conditions. Specifically, patients implanted with the Prometra Pump have undergone an MRI procedure without removing the drug from the pump prior to the procedure. Strong magnetic fields, such as those created in Magnetic Resonance Imaging (MRI) devices, may cause the valves of the pump to open, resulting in the immediate discharge of the contents of the drug reservoir and catheter into the patient leading to a potential drug overdose.

Warnings and instructions related to the MRI Conditions for Safe Scanning in the Instructions for Use (IFU) have been strengthened and expanded in a new version of the IFU, PL-91790-07. In addition, to provide an easy access Reference Guide, a new document has been written, which contains all of the MRI information from the IFU. Please see *Reference Guide: MRI Conditions for Safe Scanning for Prometra Programmable Pump*, PL-81780-00, effective September 2016.

Reason:
Flowonix Medical is distributing this Field Safety Notice to increase the awareness of warnings related to MRI Conditions for safe scanning of the Prometra Pump, and to distribute revised Instructions for Use, which provides strengthened and expanded instructions. The Prometra Pump remains categorized as **MR Conditional**. Flowonix Medical is taking this action to help reduce future occurrences of drug overdose or injury as a result of undergoing an MRI procedure without following the proper procedures.

Status of CE Mark:
As notified to customers in July, BSI, the Notified Body for Flowonix Medical, suspended the CE Mark for the Prometra Pump, Catheter and Programmer. On August 23, 2016, BSI reinstated CE Certificate CE 558455 to include the Prometra Programmer (REF 91828 and 92828) and Catheter Kit (REF 91823). On 19 September 2016, BSI lifted the CE suspension and **reinstated the CE Certificate for the Prometra Programmable Pump (REF 91827)**.

For clarification, the following table provides CE mark information for the products included in the Prometra® Programmable Pump System:

REF	Name	CE Certificate ID
91827	Prometra Programmable Pump	CE 558455
91828 92828	Prometra Programmer	CE 558455
91823	Catheter Kit	CE 558455
91824	Catheter Access Port Kit	CE 560611
91825	Refill Kit	CE 560611
91826	Tunneler	CE 560611
91830	Catheter Revision Kit	CE 560611
91840	Prometra Programmer Print Tool Kit	CE 560611
92860	Patient Therapy Controller	CE 560611
92861	Physician Configuration Device	CE 560611

Risk to Health:
The magnetic force from an MRI procedure can cause the valves within the Prometra Programmable Pump to open, which could allow the contents of the pump's reservoir to empty directly into the patient. This could cause an overdose that could result in severe injury or death. In addition, although no events or complaints have been reported to date, a theoretical risk of tissue damage could occur if an MRI procedure is performed prior to complete healing of the implantation surgical site. Therefore, warnings have been added to avoid MRI procedures until complete healing occurs. The Instructions for Use clarify that the Prometra Pump can be safely scanned after the pump reservoir is completely emptied of drug, and with an MRI device with a static magnetic field of 1.5 Tesla.

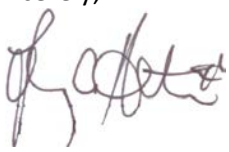
Actions to be taken by Distributors, Customers and Clinicians:

1. Acknowledgement Form: Promptly complete the attached "Acknowledgment Form" and return it to Flowonix Medical per the instructions on the form.
2. Read the attached Prometra Programmable Pump Instructions for Use, and the Reference Guide: MRI Conditions for Safe Scanning for Prometra Programmable Pump. These documents are also available at www.flowonix.com.
3. For patients requiring an MRI procedure: Ensure that all drug is removed from the pump prior to all MRI procedures, and follow all MRI scanning conditions, including the pre-MRI and post-MRI instructions in the Instructions for Use.
4. As part of the ongoing Flowonix MRI Safety Awareness Program, continue to provide a copy of the enclosed "Patient Outreach Letter", along with supplied implant cards, and medical alert bracelets to patients who have already been implanted with a Prometra Pump.
5. Forward this notice to staff and all those who need to be aware of the MRI Conditions for Safe Scanning for the Prometra Pump within your organization.
6. Distributors: Forward this notice to all customers who have received a Prometra Programmable Pump.

Contact Reference Person:
Should you have any questions or concerns, please contact your local Flowonix Medical representative or Flowonix Customer Care. We regret any inconvenience that this action may cause and appreciate your understanding as we take action to ensure patient safety and customer satisfaction. Thank you in advance for your cooperation.

The undersigned confirms that this notice has been reported to the appropriate Regulatory Agency.

Sincerely,



Larry C. Heaton II
President and Chief Executive Officer
Flowonix Medical Inc.

Company Address:
Flowonix Medical, Inc.
500 International Drive
Suite 200
Mt. Olive, NJ 07828

24-Hour Customer Care Telephone: +1 (844) 229-6729
Fax: (973) 426-0035
Email: customercare@flowonix.com

Enclosures:
Acknowledgment Form, Field Safety Notice, FSCA 2016-01
Frequently Asked Questions (FAQ's) Related to Field Safety Notice
Flowonix MRI Safety Awareness Program: Patient Outreach Letter, PL-16001-00
Prometra® Programmable Pump Instructions for Use, PL-91790-07
Reference Guide: MRI Conditions for Safe Scanning for Prometra Programmable Pump, PL-81780-00

FLOWONIX

ACKNOWLEDGMENT FORM

URGENT FIELD SAFETY NOTICE, FSCA 2016-01

FLOWONIX MEDICAL, PROMETRA® PROGRAMMABLE PUMP

CUSTOMER/ DISTRIBUTOR/ PHYSICIAN NAME_____

Date _____

Address _____

City _____

Country _____

☐ I confirm that I received the "**Urgent Field Safety Notice"** involving the update to the MRI Warnings and Instructions for the Prometra® Programmable Pump.

Signature: _____

Printed Name: _____

Title: _____

Instructions:

Complete this form and provide it to your Sales Representative or email to Flowonix at questions@flowonix.com

FAQ's Related to Field Safety Notice, Prometra® Programmable Pump

FSCA-2016-01 BSI 07/2016/01-Rev 2- Follow Up Report

Information for Patients:

1. **Is the Prometra® pump safe?**
   All medical devices and medical procedures involve risk. Risks exist related to having an MRI procedure with a Prometra pump implanted. ALL DRUG MUST BE REMOVED FROM THE PUMP PRIOR TO EXPOSURE TO AN MRI ENVIRONMENT. FAILURE TO REMOVE DRUG FROM THE PUMP MAY RESULT IN SERIOUS INJURY OR DEATH.

2. **How will this affect my ongoing care? Am I at any greater risk?**
   The risks associated with a Prometra pump implant have not changed. You are not at a greater risk at this time. The Instructions for Use have always indicated that you MUST have drug removed from your pump before you have an MRI procedure.

Information for Clinicians and Risk Managers regarding MRI Procedures:

3. **Have there been illnesses or injuries related to Prometra Pump and MRI Procedures?**
   In 2015, in the EU, a report was received of a drug overdose in a patient who entered an MRI without having the drug removed from the pump. In the U.S., there have been incidences where patients who did not comply with the labeling and underwent an MRI without first emptying the pump experienced drug overdoses. There have been two patients in the U.S. who died after having an MRI without first having the drug removed.

4. **If a patient needs to have an MRI, does the device need to be explanted? I have seen (old) information on the internet saying that the pump needs to be explanted if the patient goes into an MRI scanner.**
   The Prometra Pump does **NOT** need to be explanted if a patient requires an MRI procedure. HOWEVER, ALL DRUG MUST BE EMPTIED FROM THE PUMP RESERVOIR PRIOR TO AN MRI PROCEDURE.

5. **What is the risk to patients who need to undergo an MRI or some form of imaging procedure?**
   There is potentially significant risk to a patient who undergoes an MRI IF THE DRUG IS NOT REMOVED FROM THE PUMP PRIOR TO THE MRI. Refer to the full MRI Instructions and Warnings included in the Prometra Instructions for Use. The *Reference Guide: MRI Conditions for Safe Scanning for Prometra Programmable Pump* also includes the full MRI Instructions and Warnings information.

Information about the CE Mark:

6. **Can I implant a Prometra® Programmable Pump which is currently in the European Union?**
   Yes, Prometra Pumps which are in the European Union are legally identified with the CE Mark CE 0086, and may be used.

7. **Will I be able to get more Prometra Pumps?**
   As the CE Mark for the Prometra Pump has now been reinstated, Flowonix may resume placing Prometra Programmable Pumps on the European market. In addition, the new Prometra® II Programmable Pump which includes a Flow Activated Valve (FAV) designed to reduce potential risk associated with MRI exposure is expected to receive CE Mark in the near term, and will be made available to customers at that time.

8. **Who in Flowonix may I speak to in order to get further information?**
   Your Flowonix Sales Representative will be able to speak with you and answer questions. Alternatively, you may send an email to questions@flowonix.com