CLINICAL INNOVATIONS

URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE RECALL -- **Ebb Complete Tamponade System (CTS-1000)**

Clinical Innovations LLC

Lot Numbers: 1214-V-424; 1214-F-403

July 9, 2015

Re: Customer Notification regarding the Ebb Complete Tamponade System (CTS-1000)

To Whom It May Concern:

This is to inform you of a voluntary global recall of Clinical Innovations' ebb Complete Tamponade System (CTS-1000) involving lot numbers 1214-V-424; 1214-F-403 . The purpose of the recall is to address the potential for a balloon leak which may affect your ability to deliver therapy, when needed. Clinical Innovations' records indicate you have received a product that is affected by this action.

Following a report that an ebb Complete Tamponade System (CTS-1000) had leaked during use, Clinical Innovations conducted an investigation on the returned device and concluded that the leakage was caused by a failure mode of the bond at distal end of the uterine balloon A balloon leak can be identified by a failure to arrest bleeding, ultrasound revealing loss of balloon volume, or blood-tinged liquid being expelled from the drainage tube. A uterine balloon with a leak may not provide the anticipated tamponade effect, requiring further intervention. **Although unlikely, death could occur due to the failure mode associated with this recall.**

In the report received, the patient had stabilized prior to the leak being noticed by the clinical team. Because there is a potential for additional interventions with a balloon leak (such as arterial embolization or surgery) required to control a postpartum hemorrhage, we are requesting that you return all unused ebb Complete Tamponade System (CTS-1000) from the above-listed lot numbers. No other Clinical Innovations products are affected by this issue.

Please provide this information to your hospitals. If you have further distributed this product, please identify your customers and notify them at once of this communication and/or contact Clinical Innovations with the contact information so that we can follow-up with the owner of the device.

Clinical Innovations is working diligently to resolve this issue. In the meantime, please quarantine any remaining product in your hospitals and complete the response card attached to this Field Safety Notice. A company representative will contact you and make arrangements for the return of the product. Clinical Innovations will provide replacement product at no charge as soon as it becomes available. If you have any questions, call Clinical Innovations, at 1-(888)-268-6222 M-F 8:00 AM- 5:00 PM MT. or your Clinical Innovations service representative.

In accordance with applicable rules, the competent authorities in your country have been notified of this corrective action.

We regret any inconvenience that this may cause. We do appreciate your patience and understanding as we make efforts to ensure that this product lives up to the high quality standards expected of Clinical Innovations products.

If you have any questions regarding this matter, you may contact me at 801-260-6097 M-F 8:00 AM – 5:00 PM MT.

Sincerely,

for Ross McQuivey M.D.

Ross W. McQuivey, M.D.
Medical Director