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

Lot Numbers: 0314-F-566; 0814-F-100; 0814-F-108; 0814-V-068

January 5, 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 ofClinical Innovations'Ebb Complete Tamponade System (CTS-1000) involving all lots manufactured since August 2014 (Lot Numbers: 0314-F-566; 0814-F-100; 0814-F-108; 0814-V-068) to address the potential for a balloon leak which may affectyour ability to deliver therapy, when needed. Clinical Innovations' records indicate you have received a product that is affected by this action.

To date, we have received sixreports of uterine balloon leakage during use. The reports and our evaluation of those reports have identified that the leak may occur from the 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 reports received to date, no patient involved requiredfurther treatment to control the hemorrhage, with the exception of additional uterotonicpharmaceuticals. 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. This action is being taken with the knowledge of the Food and Drug Administration.

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 hospital. A company representative will contact you and make arrangements for the return of the product. Clinical Innovations will provide replacement product 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.

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,

Ross W. McQuivey, M.D.
Medical Director


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