IMPORTANT SAFETY ALERT

April 16, 2013

Re: Optivantage™ DH Contrast Media Injector -
Important Safety Alert regarding Coeur, Inc. disposable 125 mL syringe

Dear Valued Customer,

At Mallinckrodt, the Pharmaceuticals business of Covidien, patient safety is of paramount concern. According to our records, your facility may have one or more Optivantage Dual-Head Contrast Media Delivery Systems (the “Optivantage injector”) in service. This letter is to call attention to a potential safety issue regarding the use of the Optivantage injector with the Coeur, Inc. (“Coeur”) 125mL empty syringe (sku #C853-0125). Using the Optivantage system with this Coeur syringe could place patients at increased risk of air injection.

The Mallinckrodt portfolio of contrast media injectors are specially designed to be used with Mallinckrodt disposable prefilled or empty syringes. The Optivantage injector uses one of two alternate faceplate designs depending on the type of syringe being used: one faceplate is for use with Mallinckrodt prefilled syringes and the other for use with Mallinckrodt empty syringes. Based on the faceplate utilized, the Optivantage injector recognizes whether the Mallinckrodt syringe is an empty or prefilled syringe. If the Optivantage injector is operating with an empty Mallinckrodt syringe, then the “Auto Fill” function ensures that the system will not enable an injection sequence until the syringe has been filled. If the Optivantage injector is operating with a Mallinckrodt prefilled syringe, then the system is enabled for injection without completing a fill sequence.

Mallinckrodt has learned that, without its knowledge or permission, Coeur is marketing and promoting a disposable angiographic 125 mL empty syringe labeled by Coeur for use with the Optivantage injector. These empty syringes have been designed by Coeur to fit and operate with the Optivantage prefilled syringe faceplate. With the prefilled syringe faceplate installed, the Optivantage injector recognizes the faceplate and operates as if the Coeur syringe is prefilled with contrast media. This configuration is not consistent with the intended design or use of the system and circumvents important safety features. In this configuration, a movement of even 1 ml in the injector’s ram would allow the injector to be enabled, and subsequently allow an injection sequence to begin even when there is no fluid (i.e., only air) in the syringe. Because of this, Mallinckrodt believes that using the Coeur 125mL syringe (sku #C853-0125) could place patients at increased risk of air injection.
The Coeur syringe package insert states that “[w]hen filling the syringe, follow manufacturer’s procedures to avoid aeration of the contrast media during filling,” yet the Auto-Fill function of the Optivantage injector will not operate with the Coeur syringe. This is because the Coeur syringe is designed to fit with a prefilled syringe faceplate. The Optivantage injector has no internally programmed instruction or procedure to allow for dealing with these syringes. The resulting manual filling of the syringe could increase the risk of improper filling, patient air embolisms or contamination of the syringe.

Finally, unlike the Mallinckrodt line of empty disposable and prefilled syringes, Mallinckrodt has not validated the compatibility or reliability of this Coeur syringe for use with Mallinckrodt injectors. Any damage to the Optivantage injector caused by the use of Coeur syringes could invalidate Mallinckrodt’s warranty.

Again, patient safety is our primary concern. If you have experienced any problems using Coeur syringes or have any questions regarding their use with Mallinckrodt equipment, please call Mallinckrodt Product Monitoring at 800-778-7898 for assistance.

Sincerely,

Thomas Smith, M.D.
Chief Medical Officer
Mallinckrodt Pharmaceuticals