



April 10, 2013

**Field Safety Notice**  
Reference Number: PC-2013-0006  
Planned IFU Update

Dear Healthcare Professional,

The purpose of this Field Safety Notice is to notify users of the CardioKinetix Parachute Guide Catheter (GC) of a planned update to the Instructions for Use (IFU) as previously discussed in conference calls or in person visits that were held in late February and early March 2013. CardioKinetix is in the process of updating the "Clinical Use Information" section of the IFU to provide additional language regarding crossing the aortic valve which is presented below:

Note: Crossing the valve without a complete assembly (Catheter, Dilator, GC) may cause damage to the aortic valve.

In addition, CardioKinetix has determined that the "Additional equipment not supplied by CardioKinetix" section of the IFU should include an option of a Multi-purpose Catheter as well as the current Pigtail Catheter; this would allow operators options based on their preference. Either a Multi-purpose Catheter or a Pigtail Catheter provides an atraumatic transition to the guidewire that allow for careful crossing of the aortic valve.

On 20 February 2013, a patient was treated with the Parachute Implant. During the procedure, there was brief mild resistance noticed when the Parachute Guide Catheter was crossing the aortic valve. The procedure was completed without complication and there were good angiographic results immediately post implant. On 21 February 2013, the patient developed new aortic regurgitation. The patient's condition worsened and required aortic valve restoration surgery.

CardioKinetix would like to remind you to follow the IFU and consider the additional language that is outlined above. Additionally, you may contact your clinical representative if you should have any questions regarding the planned update to the IFU.

CardioKinetix is committed to promoting patient safety by keeping you apprised on new information regarding the Parachute Guide Catheter and associated procedures. If you have any questions, please contact [REDACTED] Vice President, European Operations at [REDACTED] [@cardiokinetix.com](mailto:[REDACTED]@cardiokinetix.com) or +44 7500 702 108.

Sincerely,

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