Urgent Field Safety Notice

Name of affected product: PARACHUTE Delivery System
FSCA identifier: PC-2014-0020
Type of action: Removal of PARACHUTE Delivery System Lot Numbers CE14012802

Date: 06-May-2014

Dear [redacted]

CardioKinetix has identified a manufacturing issue in a specific lot of the PARACHUTE Delivery System which may result in delivery catheter device detachment. There have been no patient injuries resulting from this issue. This issue has no impact on patients who have received the PARACHUTE Implant.

We have identified that there is one affected unit as listed in the table below and therefore we have initiated a voluntary removal of this unit of the PARACHUTE Delivery System.

Type of Device	Model Name	Batch/Lot Number	Quantity
PARACHUTE Delivery System	PDS68	CE14012802	1

CardioKinetix has implemented appropriate corrective actions to address the manufacturing issue.

Action Required:

- Segregate any unused affected product. Your CardioKinetix Representative will be contacting you, or may have already contacted you, to facilitate return of any unused affected product.
- For affected product that has been used, no action is necessary. Patients that have received the PARACHUTE Implant are not affected by this Field Safety Notice and should continue to be managed with standard of care.

Additional Information:

This action is being conducted with the knowledge of the German Bundesinstitut für Arzneimittel und Medizinprodukte.

We appreciate your assistance with this matter and regret any inconvenience. If you have any questions regarding this request, please contact [redacted], German Country Manager, CardioKinetix International at +49 172 248 9088; or [redacted], CardioKinetix Director of Quality Assurance at [redacted]

Sincerely,

[redacted]
Director, Quality Assurance