Bayer HealthCare

URGENT FIELD SAFETY NOTICE

Affected products and lots:
JETSTREAM®SC Atherectomy Catheter 1.85, Catalog # 112262-002,
Lot number 160312
JETSTREAM®XC Atherectomy Catheter 2.4/3.4, Catalog # 112266-002,
Lot number 160546

FSCA-ID: SA-14-INV-04
Type of action: Return to supplier

May XX, 2014

Name
Address
Address

Legal Entity

Address
Address

Phone number

www.ri.bayer.com

Dear JETSTREAM Customer,

Bayer HealthCare is recalling the above mentioned lots of the JETSTREAM SC and XC catheters which are used with the JETSTREAM Atherectomy System. These catheters are being recalled due to an error in the expiration date which appears on the product packaging. The earliest actual expiration date for these catheters is May 2015. However, because the product is mislabeled with a later expiration date, it must be returned. If product is not used in the next few months it could create a safety hazard associated with product sterility.

This recall is not a result of customer complaint or patient injury.

Our records indicate that you have received one or more of the JETSTREAM catheters subject to this action. Please take the following actions at this time:

1. Please contact Customer Support at _____ to obtain a Return Goods Authorization (RGA) number and arrange for the return of affected JETSTREAM catheter(s). The RGA number ensures your account will be credited following receipt of your returned product.

2. Record the RGA number, along with the total number of impacted catheters being returned, on the Field Safety Corrective Action (FSCA) Response Form enclosed and send it back via facsimile or e-mail.

Bayer HealthCare

One copy of this letter has been sent to your institution – arriving at either the Cardiac Catheterization Lab or Procurement Department. Please coordinate within your institution to ensure a timely response to this Field Safety Notice.

Patient safety is Bayer's primary concern. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience. If you have questions, please contact Customer Support at _____.

The undersigned confirms that the information contained in this notice has been provided to the appropriate Regulatory Agency.

Regards,

_____
Title

Bayer HealthCare

FSCA RESPONSE FORM

Please complete and return this form via facsimile to _____ or via e-mail to _____. By returning this form, I acknowledge receipt of the Field Safety Notice.

RE: FSCA regarding JETSTREAM®SC Atherectomy Catheter 1.85, Catalog # 112262-002, Lot number 160312, and JETSTREAM®XC Atherectomy Catheter 2.4/3.4, Catalog # 112266-002, Lot number 160546

I have checked the inventory of JETSTREAM catheters at my institution and have verified the following:

☐ This institution has no JETSTREAM catheters from the affected lots remaining in inventory.

☐ This institution has JETSTREAM SC and/or XC catheters subject to this Field Safety Corrective Action:

Lot Number	Quantity Returned
160312	
160546	

Legal Entity

Address
Address

Phone number

www.ri.bayer.com

Customer/Organization Name: _____

Contact Person Name/Title: _____

Phone: _____

E-mail: _____

Address: _____

_____

RGA #: _____

Quantity being returned: _____

_____ _____

Signature Date