



**URGENT: Product Recall**

JULY 29, 2011

Dear Customer,

This is to inform you of a product recall involving:

**CardioGen-82<sup>®</sup> (Rubidium Rb 82 Generator)**

See enclosed product label

Bracco Diagnostics Inc. is voluntarily recalling CardioGen-82<sup>®</sup> (Rubidium Rb 82 Generator) and temporarily discontinuing all shipments of the product. This recall was initiated following discussions with the U.S. Food and Drug Administration (FDA) regarding reports of unexpected radiation exposure in two individuals who underwent cardiac positron emission tomography (PET) scans with CardioGen-82.

The Bracco believes that any risk of harm to individuals from the reported radiation exposure is minimal. However, this recall is being undertaken while the reported unexpected radiation exposure in the two individuals is being further investigated for product misuse and possible cGMP issues.

**We request that you immediately return all CardioGen-82 generators to Los Alamos National Laboratories for storage and disposal. Please complete and return the attached Recall Return Response Form. These units will be useful toward our open investigation.**

A Bracco representative will contact you to arrange further details involving the recall process and the return of your generator.

Patient safety is Bracco's first priority. We take this matter very seriously, and we are committed to ensuring our products meet the highest quality and safety standards.

If you have any questions or for further information, please contact Kathy Quince at 609-514-2595.

Sincerely,

Alberto Spinazzi, MD  
Senior Vice President Group Medical and Regulatory Affairs  
Bracco Diagnostics Inc.

**Bracco Diagnostics Inc.**

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