



August 15, 2011

Dear Valued Customer,

We are sending this letter to review the recent events regarding CardioGen82® (Rubidium Rb 82 Generator) PET Myocardial Perfusion Imaging (MPI) and provide you with information concerning our path forward.

On July 13th, we notified you that two individuals, who had previously undergone Rb 82 PET MPI, were traveling to/from the United States and, when crossing the border, radiation detectors detected gamma radiation emanating from them in an amount that apparently was not consistent with anticipated background levels.

Patient safety is always our top priority. With the most recent events, our activities have been centered on the correlation of patient safety, on-site CardioGen-82 use that is consistent with product labeling and our generator manufacturing process. The radiation detection investigation is ongoing. We have been working with the respective sites, individuals that crossed the border and FDA throughout this process.

During this time, we implemented several additional initiatives to facilitate our review efforts.

- **Rb82 Generator Voluntary Recall Process:** On July 25th, we notified you to cease using CardioGen82 generators, followed by Bracco officially announcing the voluntary generator recall. We included instructions to return the generators to Los Alamos National Laboratories (LANL). Currently, we are focused on the recall process and our evaluation of the recent generators in use. Your cooperation in effectively shipping generator back to LANL and submitting the completed generator return paperwork is critical to our review process.

Based on our investigation and recall parameters, **CardioGen82 generators will not be manufactured and distributed through the months of August and September.** We understand CardioGen82 PET Myocardial Perfusion Imaging is a clinically relevant procedure for your practice and the patients your serve. This is a critical time and our goal continues to focus on patient safety.

- **Clinical Assessment Program:** Bracco is conducting a clinical trial at all institutions that have administered CardioGen-82 to patients from January 2011 through July 2011. Bracco is asking CardioGen82 users to participate in this clinical trial (CGEN-105) to capture important information. Details about this study have been sent to your institution. If you have additional questions regarding this study or if you have not received the information, please contact the Clinical Research Team (Scott Rauscher 609-514-2315, Kathleen Bense 609-514-2286 or Marie Morris 609-514-2577)
- **Rb82 Generator Quality Review Program:** In addition to the functional testing of the generators that were in clinical use, we will also resume our on-site review of your daily quality control records using the Quality Review Checklist. Bracco Clinical Applications Specialists will contact you to schedule a review at your convenience. This is an opportunity to provide additional customer training and education. The objectives for both efforts are focused on evaluating generator quality control outcomes.

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Again our activities have been centered on the correlation of patient safety, CardioGen82 utility at a PET imaging facility and our generator manufacturing process. As a result, we do not have a specific timeline for returning to the market. However, you can expect to receive information regarding this recall as quickly as it becomes available. We will also provide routine bi-weekly updates regarding the status of our investigation. There are several sources to access information during this challenging time.

- Please contact your local Bracco representative or our corporate offices to address your questions or concerns.
- Bracco Professional Services Hotline at 800-257-5181
- CardioGen.com has the latest information and most recent Q & A regarding the voluntary recall.
- ASNC and SNM have posted materials and resources relating to the CardioGen82 recall.

We are committed to providing you with timely information and working with you throughout this process. If you have any questions regarding this matter or require additional assistance, please contact us. We want to thank you for your ongoing support of Bracco, CardioGen-82[®] and our Cardiac PET program.

Regards,

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