



**FOR IMMEDIATE RELEASE**

**Bracco Diagnostics Inc. Introduces New CardioGen-82® (Rubidium Rb 82 Generator) Infusion System**

**Monroe Township, October 16, 2020** – Bracco Diagnostics Inc., the U.S subsidiary of Bracco Imaging S.p.A., a leading global company in the diagnostic imaging business, announced today the FDA approval of its new CardioGen-82 infusion system to enhance automation, efficiency and simplicity in cardiac position emission tomography (PET) myocardial perfusion imaging (MPI). This next-generation infusion system model will replace the company’s current infusion system.

Vittorio Puppo, President and CEO of Bracco Diagnostics Inc. said, “The new infusion system exemplifies Bracco’s significant investment in the cardiac PET imaging modality and is the culmination of thoughtful design and feedback from healthcare providers. Developing innovative products that support clinicians in diagnosing coronary artery disease is our commitment to the patients we serve.”

**Designed for efficiency, flexibility, and ease of use**

Developed with clinicians and nuclear medicine technologists in mind, the new infusion system is elegantly designed with intuitive and ergonomic details that provide easy access to all system components while minimizing radiation exposure for staff and patients.

Other smart features enable workflow efficiencies that can save nearly an hour at the beginning of each day of patient imaging and eliminate manual record keeping. A choice of dosing options and other protocol parameters make changes in scheduling and patient needs easy to accommodate.

**Bracco’s commitment to excellence in cardiac PET imaging**

“Cardiac PET MPI with the CardioGen-82 generator has helped accurately diagnose thousands of patients since 1989,” said Kim McDaniel, Senior Director, Nuclear Medicine Sales and Market Support. “Bracco was the first company to heavily invest in the modality for the diagnosis of coronary artery disease, and our introduction of the new infusion system is one more example of our commitment to our customers and patients worldwide.”



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## Indications and Usage for CARDIOGEN-82<sup>®</sup> (Rubidium Rb 82 Generator)

CARDIOGEN-82<sup>®</sup> (Rubidium Rb 82 Generator) is a closed system used to produce rubidium Rb 82 chloride injection for intravenous administration. Rubidium Rb 82 chloride injection is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

### **IMPORTANT SAFETY INFORMATION:**

#### **WARNING: HIGH LEVEL RADIATION EXPOSURE WITH USE OF INCORRECT ELUENT AND FAILURE TO FOLLOW THE ELUATE TESTING PROTOCOL**

*Please see full prescribing information for complete boxed warning*

#### **High Level Radiation Exposure with Use of Incorrect Eluent**

Using the incorrect eluent can cause high Strontium (Sr) 82 and Sr 85 breakthrough levels (5.1)

- Use only additive-free 0.9% Sodium Chloride Injection USP to elute the generator (2.5)
- Immediately stop the patient infusion and permanently discontinue the use of the affected CARDIOGEN-82 generator if the incorrect solution is used to elute the generator (4)
- Evaluate the patient's radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow (2.10)

#### **Excess Radiation Exposure with Failure to Follow the Eluate Testing Protocol**

Excess radiation exposure occurs when the levels of Sr 82 or Sr 85 in the rubidium Rb 82 chloride injection exceed limits. (5.2)

- Record eluate volume, including waste and test volumes. (2.5)
- Strictly adhere to the generator eluate testing protocol (2.6, 2.7)
- Stop using the generator if it reaches any of its Expiration Limits (2.8)

Please see full Prescribing Information for CARDIOGEN-82 (Rubidium Rb 82 Generator) including Boxed WARNING at <https://imaging.bracco.com/us-en/products/nuclear-medicine-radiopharmaceuticals/cardiogen-82>.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

CARDIOGEN-82 is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831, by GE Healthcare, Medi-Physics, Inc., South Plainfield, NJ 07080.

CARDIOGEN-82 is a registered trademark of Bracco Diagnostics Inc.



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**For additional information about Bracco's products, and for full prescribing information, please visit <http://imaging.bracco.com/us-en>.**

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**About Bracco Imaging S.p.A.**

Bracco Imaging S.p.A., part of the Bracco Group, is a world-leading diagnostic imaging provider, headquartered in Milan, Italy.

Bracco Imaging offers a product and solution portfolio for all key diagnostic imaging modalities: X-ray imaging (including Computed Tomography-CT, Interventional Radiology, and Cardiac Catheterization), magnetic resonance imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents. Our continually evolving portfolio is completed by a range of medical devices, advanced administration systems and dose-management software. The Company operates in over 100 markets worldwide, either directly or indirectly, through subsidiaries, joint ventures, licenses and distribution partnership agreements. Bracco Imaging has a strong presence in key geographies: North America, China, Europe, Japan, Brazil, Mexico and South Korea.

Bracco Imaging's manufacturing plants operate in full compliance with the best practices and sustainable eco-friendly production processes. Manufacturing sites are based in Italy, Switzerland, Germany, Canada, China and Japan.

Bracco Imaging has a well-skilled and innovative Research and Development (R&D) organization with an efficient process-oriented approach and track record in the diagnostic imaging industry. R&D activities are located in three centers based in Italy, Switzerland and the USA. To learn more about Bracco Imaging, visit [www.braccoimaging.com](http://www.braccoimaging.com).

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