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Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

Clarity that lasts
Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

Clarity that lasts

1 hour after injection 4 hours after injection

short axis
horizontal long axis
vertical long axis

CARDIOLITE scans (SPECT) from a 62-year-old male with three prior myocardial infarctions (LFOV camera equipped with a high-resolution collimator, 64 x 64 matrix, 180° arc RAO to LPO, 64 projections, 25 s/projection)

High degree of accuracy in detection of myocardial abnormalities

In blinded studies, CARDIOLITE imaging was 83% to 96% sensitive and 79% to 100% specific in detecting myocardial infarction, when compared with final diagnoses.

Reassuring safety profile

No known contraindications
Few adverse reactions

Of 2780 patients in worldwide trials, approximately 8% experienced a transient metallic taste following injection. A few cases of transient headache, mild nausea, flushing, and non-itching rash have also been reported. In worldwide commercial experience, one patient showed signs and symptoms consistent with seizure 8 to 10 min after injection. No other adverse reactions specifically attributable to the use of CARDIOLITE have been reported.

Reference
DESCRIPTION: Each 5 mL vial contains a sterile, non-pyrogenic, lyophilized mixture of:
Tetrakis (2-methoxy isobuoy isonitrile) Copper (I) tetrafluoroborate - 1.0 mg
Sodium Citrate Dihydrate - 2.6 mg
L-Cysteine Hydrochloride Monohydrate - 1.0 mg
Mannitol - 20 mg
Stannous Chloride, Dihydrate, minimum (SnCl2·2H2O) - 0.025 mg
Stannous Chloride, Dihydrate, (SnCl2·2H2O) - 0.075 mg
Tin Chloride (Stannous and Stannic) Dihydrate, maximum (as SnCl2·2H2O) - 0.086 mg

Prior to lyophilization the pH is 5.3 to 5.9. The contents of the vial are lyophilized and stored under nitrogen.

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxidant-free Sodium Pertechnetate Tc99m Injection. The pH of the reconstituted product is 5.5 (5.0-6.0). No bacteriostatic preservative is present.

The precise structure of the technetium complex is Tc99m[MIBI]2+ where MIBI is 2-methoxy isobuty isonitrile.

INDICATIONS AND USAGE: CARDIOLITE®. Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium, and in the localization of the abnormality, in patients with suspected myocardial infarction. It is also useful in the evaluation of myocardial function using the first-pass technique.

CONTRAINdications: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, take care to assure continuous monitoring and treatment in accordance with the safe, accepted clinical procedure.

PRECAUTIONS:

GENERAL
The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure (as outlined in the full prescribing information).

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc99m Injection is added, adequate shielding of the final preparation must be maintained.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc99m Injection containing oxidants should not be used.

Technetium Tc99m Sestamibi should not be used more than six hours after preparation.

Radiochemicals should be used only by physicians who are qualified by training and experience in the safe use and handling of radiochemicals and whose experience and training have been approved by the appropriate government agency authorized to license the use of radiochemicals.

Carcinogenesis, Mutagenesis, Impairment of Fertility
In comparison with most other diagnostic technetium-labeled radiochemicals, the radiation dose to the ovaries (15.0 mrad/30mCi) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, Cu(MIBI)BF4-, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HFPT and rodent somatic cell chromosome exchange tests (all in vivo). At cytotoxic concentrations (≥20 μg/mL), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. Cu(MIBI)BF4 did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg, >600 x maximal human dose).

Pregnancy Category C
Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is also not known whether Technetium Tc99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiochemicals, especially those elective in nature, of a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers
Technetium Tc99m Pertechnetate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use
Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient metallic or bitter taste immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing and non-itching rash have also been attributed to administration of the agent. One patient demonstrated signs and symptoms consistent with sepsis, 6 to 10 minutes after administration of the drug. No other adverse reactions specifically attributable to the use of Technetium Tc99m Sestamibi have been reported.

DOSEAGE AND ADMINISTRATION: The suggested dose range for I.V. administration to be employed in the average patient (70 kg) is:

370 to 110 MBq (10 to 30 mCi)
The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (See also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration (see also CLINICAL PHARMACOLOGY section in full prescribing information).

The patient dose should be measured by a suitable radiactivity calibration system immediately prior to patient administration. Radiochemical purity should be checked prior to patient administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Store at room temperature (15 to 30°C) before and after reconstitution.

RADIATION Dose: Table 4 shows the radiation doses to organs and tissues of an average patient (70 kg) per 1110 MBq (30 mCi) of Technetium Tc99m Sestamibi injected intravenously.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

<table>
<thead>
<tr>
<th>Organ</th>
<th>Dose/ 4.8 hour void</th>
<th>Dose/ 2.0 hour void</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30 mCi 1110 MBq</td>
<td>30 mCi 1110 MBq</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.2</td>
<td>2.0</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>2.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Small Intestine</td>
<td>3.0</td>
<td>30.0</td>
</tr>
<tr>
<td>Upper Large</td>
<td>5.4</td>
<td>55.5</td>
</tr>
<tr>
<td>Intestine Wall</td>
<td>3.9</td>
<td>40.0</td>
</tr>
<tr>
<td>Intestinal Wall</td>
<td>5.6</td>
<td>6.1</td>
</tr>
<tr>
<td>Stomach Wall</td>
<td>0.5</td>
<td>5.1</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>20.0</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.6</td>
<td>5.8</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>5.8</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.7</td>
<td>2.8</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7</td>
<td>6.8</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.7</td>
<td>7.0</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5</td>
<td>15.5</td>
</tr>
<tr>
<td>Testes</td>
<td>0.3</td>
<td>3.4</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5</td>
<td>5.1</td>
</tr>
<tr>
<td>Urinary Bladder</td>
<td>0.5</td>
<td>4.8</td>
</tr>
<tr>
<td>Total Body</td>
<td>2.0</td>
<td>20.0</td>
</tr>
</tbody>
</table>


HOW SUPPLIED: Du Pont’s CARDIOLITE®. Kit for the preparation of Technetium Tc99m Sestamibi is supplied as a 5 mL vial in kits of two (2), five (5) and thirty (30) vials, sterile and non-pyrogenic.

Prior to lyophilization the pH is between 5.3 and 5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at room temperature (15 to 30°C) before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives.

In each of two (2) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each of five (5) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each of thirty (30) vial kit is one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The US Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material identified in 35.100 and 35.200 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

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DESCRIPTION: Thallium Chloride TI 201 is supplied in isotonic solution as a sterile, non-glycerin diagnostic radiopharmaceutical for intravenous use. The aqueous solution at the time of calibration contains 37MBq/ml (1mCi/ml) Thallium Chloride TI 201. The pH is adjusted with hydrochloric acid and/or sodium hydrosulfide solution. It is made isotonic with 9mg/ml sodium chloride and is preserved with 8mg/ml benzyl alcohol.

Thallium TI 201 is coagulation produced with no carrier added and contains no less than 58% Thallium TI 201 as a percentage total activity with contaminants less than 0.3% Thallium TI 201. 1.2 Thallium TI 201 and 0.2% Lipo Pd 203 expressed as a percentage of TI 201 activity at calibration. It is recommended that Thallium Chloride TI 201 be stored close to calibration time to minimize the effect of higher levels of radionuclide contaminant.

INDICATIONS AND USAGE: Thallium Chloride TI 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction. It may also have prognostic value regarding survival, when used in clinically stable patients following the onset of symptoms of an acute myocardial infarction, to assess the size and site of the perfusion defect. Thallium Chloride TI 201 may be used to decrease stress testing and as an adjunct in the diagnosis of ischaemic heart disease (atherosclerotic coronary artery disease).

Lithium TI 201 may be used to assess myocardial infarction, or to differentiate between recent myocardial infarction and ischemia.

Thallium Chloride TI 201 is indicated also for the localization of sites of parathyroid hyperactivity in patients with elevated serum calcium and parathyroid hormone levels. It may also be useful in the operative screening to locate extrathyroidal and mediastinal sites of parathyroid hyperactivity and for post-surgical reassessment. Thallium Chloride TI 201 has not been adequately demonstrated to be effective for the localization of normal parathyroid glands.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom myocardial infarction or ischemia is known or suspected, care should be taken to assure continuous clinical monitoring and treatment in accordance with accepted medical practice. The procedure and the stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

PRECAUTIONS: Precautions are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as found in diabetes mellitus) on the quality of Thallium Chloride TI 201 scans. Attention is directed to the fact that thallium is a potassium analog, and since the transport of potassium is affected by these factors, the possibility exists that the thallium may likewise be affected.

GENERAL: Do not use after the expiration time and date (5 days maximum after calibration time) stated on the label.

Do not use if contents are turbid.

The patient dose should be monitored by a suitable radiopharmacology system immediately prior to administration.

Thallium Chloride TI 201, as all radiopharmaceuticals, must be handled with care and used with appropriate safety measures to minimize external radiation exposure to medical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

Cardiovascular, Metabolic, Impairment of Fertility: No long-term animal studies have been performed to evaluate the carcinogenic potential of the radiopharmaceutical, especially those selective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the completion of pregnancy.

Pregnancy Category C: Adequate reproductive studies have not been conducted in animals with Thallium Chloride TI 201. It is also not known whether Thallium Chloride TI 201 can cause fetal harm when administered to pregnant animals. However, Thallium Chloride TI 201 should not be given to a pregnant woman except when benefits clearly outweigh the potential risks.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, nursing should not be undertaken when a patient is administered radiopharmaceutical material.

Pediatric Use: Safety and effectiveness in children below the age of 18 have not been established.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the use of radiopharmaceuticals and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

ADVERSE REACTIONS: A single adverse reaction to the administration of Thallium Chloride TI 201 has been reported. It is a reaction of hypotension accompanied by pruritus and a diffuse rash which responded to antihistamines and steroids within one hour.

HOW SUPPLIED: Thallium Chloride TI 201 for intravenous administration is supplied as a sterile, non-glycerin solution containing at calibration time 37MBq/ml (1mCi/ml) of Thallium Chloride TI 201, 9mg/ml sodium chloride, and 8mg/ml benzyl alcohol. The pH is adjusted with hydrochloric acid and/or sodium hydrosulfide solution. Vials are available in the following quantities of radioactivity: 81.4, 182, 264, 348B (2.2, 3.3, 4.4, 6.6, 8.8 and 9.9mc) of Thallium Chloride TI 201.

Store at room temperature (15-30°C).

DU PONT PHARMA

Radiopharmaceuticals

Du Pont Radiopharmaceuticals, Inc.
331 Treble Cove Road
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References:
8. Davis on file, Boehringer Ingelheim Pharmaceuticals, Inc.
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<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract Form</td>
<td>October Issue</td>
<td>1/7/92</td>
</tr>
<tr>
<td>Scientific Papers</td>
<td>Contact SNM,</td>
<td>1/14/92</td>
</tr>
<tr>
<td></td>
<td>Attn: Meetings Dept.</td>
<td></td>
</tr>
<tr>
<td>Scientific Exhibits</td>
<td>November Issue</td>
<td>5/8/92</td>
</tr>
<tr>
<td>Registration Form</td>
<td>December Issue</td>
<td>5/15/92</td>
</tr>
</tbody>
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1992 Scientific Program Committee, Scientific Exhibits Subcommittee, and the Scientific & Teaching Sessions Committee solicit the submission of abstracts from members and nonmembers of The Society of Nuclear Medicine for the 39th Annual Meeting in Los Angeles, CA. Scientific Paper abstracts accepted for the program will be published in a supplement to the May issue of The Journal of Nuclear Medicine and accepted Technologist Section abstracts will be published in the June issue of the Journal of Nuclear Medicine Technology. Abstracts accepted for Society Program Scientific Exhibits will not be published. Original contributions on a variety of topics related to nuclear medicine will be considered, including:

- Instrumentation and Data Analysis
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- Nuclear Magnetic Resonance
- Clinical Science Applications
- Bone/Joint
- Cardiovascular (clinical and basic)
- Endocrine
- Gastroenterology (clinical and basic)
- Immunology (antibody)
- Pediatrics
- Pulmonary
- Renal/Electrolyte/Hypertension
- Hematology/AIDS
- Oncology (non-antibody)

Authors seeking publication for the full text of their papers are strongly encouraged to submit their work for immediate review to the JNM, and for the technologist section, to the JNMT.

DEADLINES

For receipt of abstracts for SCIENTIFIC PAPERS
is Tuesday, January 7, 1992.

For receipt of abstracts for SCIENTIFIC EXHIBITS
is Tuesday, January 14, 1992.

There are two abstract forms for this year's meeting. The Scientific Paper abstract form can be obtained in the October 1991 JNM. The Scientific Exhibits abstract form is only available by calling or writing:

The Society of Nuclear Medicine
136 Madison Avenue, New York, NY 10016-6760
Tel: (212) 889-0717 FAX: (212) 545-0221 

THE SOCIETY OF NUCLEAR MEDICINE
MID-WINTER MEETING

**Title:** Computer and Instrumentation: Toward the 21st Century
**Location:** Hyatt Regency DFW, Dallas, TX
**Date:** Monday-Tuesday, February 10-11, 1992
**Sponsor:** The Computer and Instrumentation Council of The Society of Nuclear Medicine
**CME Credit:** Approximately 12 Hours AMA Category I
**VOICE Credit:** Approximately .9 CEUs available for VOICE Credit for Technologists
**Seminar Notes:** Registration includes a luncheon on Monday, February 10th, with a guest speaker. There are a limited amount of lunches available so please register early.

**THE FEE**

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<th>Before 12/20</th>
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<td>Physicians/Scientists</td>
<td>$175.00</td>
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**ALL PRE-REGISTRATIONS MUST BE RECEIVED BY JANUARY 17, 1992**

**COMPUTER AND INSTRUMENTATION: TOWARD THE 21ST CENTURY**
Hyatt Regency DFW, Dallas, TX • Monday, February 10 — Tuesday, February 11, 1992

**PLEASE ENROLL THE FOLLOWING**

Name (as it should appear on badge)

Affiliation

Address

City State Zip Phone

MAIL TO:
THE SOCIETY OF NUCLEAR MEDICINE
COMPUTER and INSTRUMENTATION SYMPOSIUM
Department of Meeting Services
136 Madison Avenue
New York, NY 10016-6760 • (212) 889-0717

I wish to pay by: □ Check □ VISA □ MasterCard

Card Number Expiration Date

Signature

$ Amount Enclosed (see above)

To make hotel reservations, call the Hyatt Regency DFW direct at (214) 453-1234, indicate you are with The Society of Nuclear Medicine. Please make your reservations by January 10, 1992. Do NOT mail housing information to The Society.
Information for Classified Advertisers—1991

POLICY: The Journal of Nuclear Medicine and the Journal of Nuclear Medicine Technology accept classified advertisements from medical institutions, groups, suppliers, and qualified specialists in nuclear medicine. Acceptance is limited to Positions Open, Positions Wanted, Equipment Available, Equipment Wanted, and Seminars. We reserve the right to decline, withdraw, or modify advertisements.

LINE-ADS: $19.00 (JNM) or $17.00 (JNMT) per line or fraction of line (approx. 50 characters per line, including spaces). Please allow 28 characters for the first line which will appear in capital letters. Special Positions Wanted rate for SNM members: $10.00 per line. Note: Box numbers are available for the cost of the two lines required.

EXAMPLES

NUCLEAR MEDICINE TECHNOLOGIST. Registered or registry eligible technologist to work in private office. Special emphasis on nuclear cardiology. Salary negotiable. Send resume to: Box 1203, The Society of Nuclear Medicine, 136 Madison Ave., 8th fl., New York, NY 10016-6760. EOE.

WITH BOX NUMBER
COST: 6 lines x $19.00 = $114.00 (JNM)
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JNM
Full page $1,300
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For further information please contact Lisa Esposito at (212) 889-0717.
**APPLICATION FOR MEMBERSHIP**

(see reverse side for instructions)

**First Name** Dr, Mr, Mrs, Ms, Miss (CIRCLE ONE)  
**Middle Initial**  
**Last Name** Jr, Sr, I, II, III (circle one)

_______

Check Degree(s) Earned:  
MD    PhD    MA    MS    BA    BS    AA    AS    Other

Indicate Board Certification(s):  
☐ ABNM  ☐ ABR  ☐ ABP  ☐ ABIM  ☐ ABSNM  ☐ ABHP  ☐ NMTCB

☐ ASCP  ☐ ARRT(N)  ☐ ARRT(T)  ☐ ARRT(R)  ☐ Other

Please choose ONLY ONE of the following categories of membership for which you wish to be considered. (Categories of membership are described on the front page of this application and should be reviewed carefully before your choice is made.)

☐ Full  ☐ Associate  ☐ Technologist  ☐ Affiliate

Please check ONE box for preferred mailing address, but complete both columns for our files:

☐ Institutional  ☐ Home Address

**DIVISION**

**STREET ADDRESS**

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**CITY**

**STATE/PROVINCE/COUNTRY**

**ZIP CODE**

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**AREA CODE**

**TELEPHONE NO.**

**STREET ADDRESS**

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**STATE/PROVINCE/COUNTRY**

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**AREA CODE**

**BUSINESS TELEPHONE NO.**

**EXT.**

**FAX NUMBER**

**IN-TRAINING STATUS**

☐ YES  ☐ NO

Projected Completion Date: _______ month/year

Program Director _______

PROGRAM DIRECTOR'S TELEPHONE NO. _______

Would you like to join the TECHNOLOGIST SECTION?  
☐ Yes  ☐ No

(Note: Technologist members automatically become technologist section members)

**COUNCIL MEMBERSHIP**

☐ Academic Council  ☐ Computer/Instrumentation Council  ☐ Radioassay Council

☐ Brain Imaging Council  ☐ Correlative Imaging Council  ☐ Radiopharmaceutical Council

☐ Cardiovascular Council  ☐ Nuclear Magnetic Resonance Council

**NAME OF SNM MEMBER WHO SUGGESTED THAT YOU JOIN**

(optional)

**APPLICANT'S SIGNATURE**

____________________________  ________________

**DATE**

FOR OFFICE USE ONLY

☐ MF  ☐ TS  ____________  CHAIRMAN, MEMBERSHIP COMMITTEE (sign)

APPLICATION FEE  ______________  ☐ MA  ☐ IT  ____________  TECHNOLOGIST SECTION DESIGNEE (sign)

CHAPTER  ______________  ☐ MTT

ACCOUNT #  ______________  ☐ ML

2/91
TECHNOLOGIST JOB NETWORK

The New England Chapter—SNM/TS announces "The Job Hotline," a national toll-free, hotline for nuclear medicine. The hotline is designed to provide a quick link for technologists seeking jobs and for hospitals seeking technologists. Institutions seeking technologists should call the hotline number, leave the name of the institution, title of the job opening, and name and number of the contact person; data are then stored for three months in a database for anyone who calls the hotline seeking employment. Technologists seeking employment should call the hotline number, specify state(s) which are of interest, specify type of job desired, and leave name and address. A listing will then be sent out in 48 hours; all inquiries are kept confidential. If an opening has not been filled within three months, the institution should call again to have it listed. The institution should also call if an opening has been filled so that it can be deleted from the database. The hotline numbers are 1-800-562-6387 (1-800-JOB-NETS) or 1-990-4212 in Maine. Questions or comments should be directed to: Tom Starno, Manager, Job Hotline, New England Chapter—TS at (207) 945-7186.

The Mideastern Chapter—SNM/TS will provide a referral network for technologists seeking employment and for hospitals in need of technologists. Interested individuals should call Cathy Gonzalez at (301) 855-1712. Please leave your name, address, phone number and a brief description of your request.

NOTE: SNM chapters are invited to submit job referral service listings for publication. Pertinent information—name and brief description of the service, telephone number and/or address, name or number of contact person for inquiries—should be sent to:

Leigh Silverman, Section Editor, SNM JNM. The Society of Nuclear Medicine, 136 Madison Avenue New York, NY 10016-6760.

CardioGan-82
Rubidium Rb 82 Generator

INDICATIONS AND USAGE
Rubidium chloride Rb 82 injection is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected myocardial infarction.

CardioGan-82 (Rubidium Rb 82 Generator) must be used with an infusion system specifically labeled for use with the generator and capable of accurate measurement and delivery of doses of rubidium chloride Rb 82 injection not to exceed a single dose of 2220 MBq (60 mCi) and an additive dose of 4440 MBq (120 mCi) at a rate of 50 mL/min with a maximum volume per infusion of 100 mL and a cumulative volume not to exceed 200 mL. These performance characteristics reflect the conditions of use under which the drug development clinical trials were conducted.

Adequate data from clinical trials to determine precise localization of myocardial infarction or identification of stress-induced ischemia have not been collected.

Positron emission tomographic (PET) instrumentation is recommended for use with rubidium chloride Rb 82 injection.

CONTRAINDICATIONS
None known.

WARNINGS
Caution should be used during injection as patients with congestive heart failure may experience a transient increase in circulatory volume load. These patients should be observed for several hours following the Rb-82 procedure to detect delayed hemodynamic disturbances.

PRECAUTIONS
General
Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of rubidium chloride Rb 82 solutions. Attention is directed to the fact that rubidium is physiologically similar to potassium, and since the transport of potassium is affected by these factors, the possibility exists that rubidium may likewise be affected.

Rubidium chloride Rb 82 injection must be administered only with an appropriate infusion system capable of meeting the performance characteristics previously described. (See INDICATIONS AND USAGE). The drug should be used only by those practitioners with a thorough understanding of the use and performance of the infusion system.

Repeat doses of rubidium chloride Rb 82 injection may lead to an accumulation of the longer lived radioactive contaminants strontium Sr 82 and strontium Sr 85. Since eluate obtained from the generator is intended for intravenous administration, aseptic techniques must be strictly observed in all handling. Only additive free Sodium Chloride Injection USP should be used to elute the generator. Do not administer eluate from the generator if there is any evidence of foreign matter.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to ensure minimum radiation exposure to occupational workers. Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or to determine whether rubidium Rb 82 may affect fertility in males or females.

Pregnancy Category C
Animal reproductive studies have not been conducted with rubidium Rb 82. It is also not known whether rubidium Rb 82 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Rubidium Rb 82 should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those examinations which are elective in nature, in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers
It is not known whether rubidium Rb 82 is excreted in human milk. Due to the short half-life of rubidium Rb 82 (75 sec) it is unlikely that the drug would be excreted in human milk during lactation. However, because many drugs are excreted in human milk, caution should be exercised when rubidium Rb 82 is administered to nursing women.

Pediatric Use
Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
No adverse reactions specifically attributable to rubidium Rb 82 have been reported during controlled clinical trials.

HOW SUPPLIED
CardioGan-82 (Rubidium Rb 82 Generator) is supplied in the form of strontium Sr 82 adsorbed on a hydroxyl stannic oxide column with an activity of 90-150 millicuries Sr 82 at calibration time. The generator is encased in a lead shield surrounded by a labeled plastic container. Complete assay data for each generator are provided on the container label. CardioGan-82 (Rubidium Rb 82 Generator) is intended for use only with an appropriate, properly calibrated infusion system labeled for use with the generator.

600-501 Issued: March 1991

Circle Reader Service No. 77

SNM 39th Annual Meeting
Critical Dates

<table>
<thead>
<tr>
<th>Item</th>
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<td>Abstract Form</td>
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<td>Registration Form</td>
<td>November Issue</td>
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<td>December Issue</td>
<td>May 15, 1992</td>
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DON'T FORGET THE MID-WINTER MEETING IN DALLAS, TX

DATE: February 10-11, 1992
LOCATION: Hyatt Regency DFW, Dallas, TX
SPONSOR: The Computer and Instrumentation Council
We’ve removed your PET collar

PET perfusion studies without a cyclotron

CardioGen-82® (Rubidium Rb 82 Generator) is the only generator-based myocardial perfusion agent indicated for PET imaging.

Now in 45 to 60 minutes you can have PET images to help you distinguish normal from abnormal myocardium. All without the expense of a cyclotron!

The short 75-second half-life lowers the radiation burden to the patient. When incorporated into the Rubidium Infusion System, serial imaging of myocardial blood flow changes can be performed as often as every ten minutes.

The CardioGen-82 System also improves patient throughput and scheduling efficiency by enabling you to perform multiple studies in a short time.

Remove the PET collar from your department. Get the PET images you need in 45 to 60 minutes, without a costly cyclotron.

CardioGen-82®
Rubidium Rb-82 Generator

Please see adjacent page for brief summary of prescribing information.

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