The E.CAM offers extensive cardiac-specific assessment tools that increase clinical quality and accuracy. The result...an unsurpassed level of clinical confidence.

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  - EF, volumes and mass
  - Wall motion analysis
  - Defect extent/reversibility maps
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RSNA Booth #6750.
The CAPRAC-R Well Counting System offers:
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- Economy
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- Dicopac®
- Blood Volume (Cr-51 & I-125)
- Wipe Tests
- Leak Testing

Using the General Counting Section, the CAPRAC-R can replace older systems for any type of gamma counting that performs RIA’s or other lab procedures.

WIPE TEST COUNTING

The CAPRAC-R monitors ultra-low levels of activity in as little as 6 seconds using Nal detector for 1 nCi while giving preliminary isotope identification through gamma spectroscopy.

An Epson printer is optional. A choice of detectors are also available: the standard 1-1/2” Nal detector or a 2” x 2” Nal crystal with 1” shielding.

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RSNA Booth #2601.
Inside Information.

Perfusion and function in one test: clinically relevant information.

Cardiolite® provides:

- Both stress perfusion and resting function (wall motion, wall thickening, a quantifiable and reproducible measure of ejection fraction)\(^1,2\)
- Enhanced diagnostic confidence with a high negative predictive value: A normal stress test correlates with a <1% annualized cardiac event rate\(^3,5\)
- Clinically relevant information in a range of situations—such as risk assessment, evaluation post-MI, and for chest pain management

For more information, contact DuPont Pharma at 1-800-362-2668 or www.radiopharm.com

There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi. Please see brief summary of prescribing information on adjacent page.

Cardiolite®
Kit for the preparation of Technetium Tc99m Sestamibi

The Confidence You Want—The Information You Need
**Cardiolite®**

*Kit for the preparation of Technetium Tc99m Sestamibi*

**FOR DIAGNOSTIC USE**

**INDICATIONS AND USAGE:** CARDIOLITE®, Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects), in evaluating myocardial function and developing information for use in patient management decisions. CARDIOLITE® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (e.g., exercise or pharmacologic stress in accordance with the pharmacologic stress agent’s labeling).

It is usually not possible to determine the age of a myocardial infarction or to differentiate a recent myocardial infarction from ischemia.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with accepted clinical procedure. Infrequently, death has occurred to 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (see PRECAUTIONS).

Pharmacologic stress may be associated with serious adverse events such as myocardial infarction, arrhythmias, hypotension, bronchospasm, and cerebrovascular events. Caution should be used when pharmacologic stress is selected as an alternative to exercise; it should be used when indicated and in accordance with the pharmacologic stress agent’s labeling.

**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 preparatory procedure.

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 patient 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, use of Pertechnetate Tc99m Injection containing oxidizing agents should not be used.

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

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

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

The most frequent exercise stress test endpoints, which resulted in termination of the test during controlled Tc99m Sestamibi studies (two-thirds were cardiac patients) were:

- Fatigue 35%
- Dyspnea 17%
- Chest Pain 16%
- ST-depression 7%
- Arrhythmia 4%

**Cardiolite**

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is also not known if 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.

**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 paraesthesia and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing, edema, injection site inflammation, dizziness, nausea, vomiting, pruritis, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, anaphylaxis as well as other reactions to administration of the agent. Cases of angina, chest pain, and death have occurred (see WARNINGS and PRECAUTIONS). The following adverse reactions have been rarely reported: signs and symptoms consistent with severe occurring shock (e.g., hypotension, tachycardia), anaphylactic reaction in a sensitized patient; transient idiopathic thrombocytopenic purpura, which was characterized by dyspnea, hypotension, bradycardia, and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

**DIAGNOSTIC INFORMATION:** The suggested dose range for L.V. administration in a single dose to be employed in the average patient (70kg) is: 2.30mCi (110.5MBq) or 3.45mCi (129.4MBq) I.V.

**REFERENCES:**


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TRIONIX Works-in-Progress

TRIONIX RESEARCH LABORATORY, INC.
PURPOSE:
Simultaneous evaluation of Metabolism and Perfusion with F-18 FDG and Tc-99m MIBI.

CALIBRATION:
- Energy Range: Both 140 keV and 511 keV isotopes in one MCA.
- Each window: Independent linearity and flood correction tables.
- Perfect Alignment of Tc-99m & F-18 DISA images.
- Acquisition of Extrinsic Flood Correction tables for 511 keV Collimator: Simultaneous for Tc-99m and F-18 in one flood pool source.

BASIC PERFORMANCE:
TRIAD
Intrinsic Energy Resolution for 511keV: 8.96 %
Intrinsic Spatial Resolution for 511keV: 0.55 mm/5mm

<table>
<thead>
<tr>
<th>Energy Window</th>
<th>Planar Sensitivity (cps/mCi)</th>
<th>Planar Resolution (mm)</th>
<th>Reconstructed Spatial Resolution (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tc-99m</td>
<td>20</td>
<td>45</td>
<td>66.5</td>
</tr>
<tr>
<td>F-18</td>
<td>52</td>
<td>6.6</td>
<td>9.3</td>
</tr>
<tr>
<td>Tc-99m</td>
<td>82</td>
<td>8.2</td>
<td>18.0</td>
</tr>
<tr>
<td>F-18</td>
<td>107</td>
<td>10.7</td>
<td>21.5</td>
</tr>
</tbody>
</table>

- Planar Spatial Resolution: Measured at 10 cm distance from collimator
- SPECT Spatial Resolution: Measured from a line source in the center of 22 cm dia. cylinder filled with water; 13 cm radius circular orbit; Recon Filter at Nyquist Frequency with pixel = 3.56mm

CARDIAC PHANTOM TEST RESULTS:
- Simultaneous Acq. of Data Spectrum Cardiac Phantom with 300mCi of F-18 and 1mCi of Tc-99m inside water-filled 22 cm cylinder.
- Two Defects inserted: 15 x 10mm and 20 x 5mm.
- SPECT Acq : 128 x 128 matrix of pixel 3.56mm; 13 cm radius rotation; 30 min. scan
- SPECT Recon: 2D Butterworth Prefilter with cutoff freq. in cyc/cm: 0.75 for Tc-99m and 0.55 for F-18 roll off 5.0 Ramp Recon Filter with Nyquist frequency.
- Data Analysis: Circumferential Profiles are compared.

DEVELOPMENT HISTORY:
1. Dr. Drake’s private communication to Dr. Chun Lim at ’93 Toronto SNM with 200 patient’s study binder. Performed by the first BIAD with High Energy Collimator.

TREND CONCLUSION:
Review of the above historical evolution of DISA shows the migration of the systems of choice from Dual-head SPECT to Triple-head SPECT to take advantage of 50% higher sensitivity.
CLINICAL INFO:
Patient: 68 yo male
History: Encasement of pericardium by tumor.

ACQ/PROC INFO:
System: TXLT 20
Pixel: 4.48 mm
Matrix: 128 x 128
Pre-Filter: Parzen
FC (cy/cm): 1.116
Isotope: 15 mCi FDG / 15 Tc-99m RBC’s
Injection to Imaging: 2 hrs
Collimator: UHE-PAR
Acq Time: 30 min

CONCLUSION:
Multiple lesions including both adrenals. Right adrenal biopsy shows large cell cancer.

Courtesy of Robert Burt, MD - University of Indiana - Indianapolis, IN
MISSION
Achieve “Quantitatively Accurate SPECT” by:
• Scatter Elimination
• Resolution Recovery
• Attenuation Correction

CONCEPT
SESAME Scatter Elimination by Spectral Acquisition Memory Extension is an acquisition-based technique which analyzes the spatial distribution of scatter by acquiring the energy spectrum at each pixel and removing the scatter content.

ACTION Attenuation Correction by Transmission Information Observation Network corrects SPECT for attenuation distortion using a measured attenuation map.

DSFR Detector Spread Function Recovery utilizes an iterative reconstruction process incorporating both the attenuation map and depth-dependent detector spread-function to correct for detector blurring.

RESULTS
QuaSAR SPECT comparison with Traditional Filtered Back-Projection (FBPJ) demonstrates improved spatial resolution and contrast, leading to better quantification.

NOTE on QuaSAR Image:
1. Clearer Separation of Point Sources.
2. Sharper Edge Definition.
3. More Uniform Background.
4. Background Level In Lung Area Nearer to True Value of Zero.
5. Improved Target to Background Ratio, Nearly 4 to 1.
ACUTE CLOT?
The ultrasound could be negative.
The venogram could be positive.

NOW...
Clinical follow-up studies of patients with negative AcuTect scans have not been performed to determine if negative image findings mean the absence of acute venous thrombosis. If a patient has clinical signs and symptoms of acute venous thrombosis, a clinical management decision to withhold treatment with anticoagulants should not be based on a negative AcuTect study alone.

After administration of AcuTect, as with the administration of other intravenous drugs, patients with a history of drug reactions, other allergies, or immune system disorders should be observed for several hours.

AcuTect™—a unique, radiolabeled synthetic peptide—is the first to offer you the ability to clearly, safely, and comfortably target acute clots. AcuTect is indicated for scintigraphic imaging of acute venous thrombosis in the lower extremities of patients who have signs and symptoms of acute venous thrombosis.

AcuTect binds preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets. The result is a sensitivity that challenges the "gold standard."

In clinical studies, blindly read AcuTect demonstrated 56-73% agreement with blindly read venography. While venography detects the presence of any clot; AcuTect appears to detect acute and not chronic venous thrombosis. (This is based on in vivo and ex vivo animal data; not confirmed clinically.) Therefore, 100% agreement between AcuTect and venography is not expected.

AcuTect is easily administered in a single, upper extremity peripheral IV injection. Imaging can begin quickly, between 10 and 60 minutes after injection.

More than just another diagnostic option—AcuTect is designed for a more confident course of treatment in a potentially life-threatening condition.

For customer service, call 1-877-DIATIDE.

AcuTect™
(Kit for the Preparation of Technetium Tc 99m Apcitide Injection)

The difference is acute.

Diatide, Inc.
BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please consult full Product Information before prescribing.

DESCRIPTION
AcuTectâ"¢ Kit for the Preparation of Technetium Tc 99m Apcitide injection, is intended for use in the preparation of technetium Tc 99m Apcitide, a diagnostic radiopharmaceutical to be used by intravenous injection. Each vial contains a sterile, nonpyrogenic, lyophilized mixture which is formulated with 100 ug of apcitide, 7.5 mg of sodium gluconate dihydrate, 85 ug of stannous chloride hexahydrate and sufficient sodium hydroxide or hydrochloric acid to adjust the pH to 7.4 prior to lyophilization. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product does not contain an antimicrobial preservative.

Bibapcitide is composed of two peptide monomers. When sterile, nonpyrogenic Sodium Percarboxylate Tc 99m in 0.3% Sodium Chloride Injection, U.S.P., is added to the vial and heated, the bibapcitide is split and forms a technetium-99m complex of apcitide.

INDICATIONS AND USAGE: AcuTectâ"¢ is indicated for scintigraphic imaging of acute venous thrombosis in the lower extremities of patients who have signs and symptoms of acute venous thrombosis.

CONTRAINDICATIONS: None known.

WARNINGS: Clinical follow-up studies of patients with negative AcuTectâ"¢ scans have not been performed to determine the true negative image findings mean the absence of acute venous thrombosis. If a patient has clinical signs and symptoms of acute venous thrombosis, a clinical management decision to withhold treatment with anticoagulants should not be based on a negative AcuTectâ"¢ study alone.

Other adverse events which occurred in a <0.5% of patients following receipt of AcuTectâ"¢ included: agitation, asthma, bronchitis, cardiovascular disorder, chills, conjunctivitis, dyspnea, fever, hypomania, injection site reaction, livor mortis, nausea, palmar, paresthesia, pruritus, rash, tachycardia, twitch, urticaria, and vomiting.

OVERDOSAGE: Clinical consequences of overdose with technetium Tc 99m Apcitide have not been studied.

USAGE:

Tc 99m Apcitide should be drawn into the syringe and administered using sterile technique. If nonpyrogenic equipment is used, intravenous use should be limited to prevent residual contamination with traces of cleansing agents. Aseptic technique is a must and the product should be discarded appropriately. (See Instructions for Preparation Section of Full Product Information.)

Lower Extremity Imaging
AcuTectâ"¢ imaging should begin between 10 and 60 minutes after injection. Patients should void just before imaging in order to limit the influence of urinary bladder radioactivity since technetium Tc 99m Apcitide is cleared from the blood by the kidneys. If it is determined that imaging needs to be repeated, additional images may be obtained up to 180 minutes without reiteration. The safety of more than one dose has not been studied.

Positive AcuTectâ"¢ uptake in the deep venous structures is defined as asymmetric vascular uptake (with or without superimposed portal uptake) in contrast enhanced images, and asymmetry in both anterior and posterior projections. If asymmetry appears only after extreme contrast enhancement, then diffuse asymmetry must also be present for an image to be considered as positive.

Superficial increased uptake is not to be interpreted as acute deep venous thrombosis.

RADIATION DOSE

Based on human data, the absorbed radiation dose to an average adult (70 kg) from an intravenous injection of technetium Tc 99m Apcitide are listed in Table 2. The values are listed in descending order as rad/mCi and mrad/MCg and assume urinary bladder emptying at 4.8 hours.

<table>
<thead>
<tr>
<th>Table 2: Radiation Absorbed Doses for a 370mg Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organ</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
</tr>
<tr>
<td>Kidneys</td>
</tr>
<tr>
<td>Upper Large Intestine Wall</td>
</tr>
<tr>
<td>Lower Large Intestine Wall</td>
</tr>
<tr>
<td>Uterus</td>
</tr>
<tr>
<td>Thyroid Gland</td>
</tr>
<tr>
<td>Testes/Ovaries</td>
</tr>
<tr>
<td>Lungs</td>
</tr>
<tr>
<td>Red Marrow</td>
</tr>
<tr>
<td>Breast</td>
</tr>
</tbody>
</table>

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1 rev., Soc. Nucl. Med., 1976). Effective dose equivalent was calculated in accordance with ICRP 50 (Ann. ICRP 18, 1-4, 1988) and gave a value of 0.0008mSv/mCi (0.00003 rem/mCi).

HOW SUPPLIED
Each kit contains one vial containing a sterile, nonpyrogenic, freeze-dried mixture of bibapcitide, stannous chloride dihydrate and sodium gluconate dihydrate, together with a package insert and adverse event reporting cards. Tests are available in packs of 5 vials.

Rx only

1. Store the kit in a refrigerator at 2 to 8°C (36 to 46°F). Store the reconstituted injection solution at 20 to 25°C (68 to 77°F), using appropriate radiation shielding, for up to 6 hours.

2. Use only

(1996) Distributed by Diatide, Inc. and Nycormed Amersham
63-0819110

AcuTectâ"¢ is a trademark of Diatide, Inc.

The difference is acute.

Diatide, Inc.
BRIEF SUMMARY

For Intravenous Infusion Only

DESCRIPTION

Adenosine is an endogenous nucleoside occurring in all cells of the body. It is chemically 6-amino-β-D-ribonucleoside-9-H-purine.

Adenosine is a white crystalline powder. It is soluble in water and practically insoluble in alcohol. Solubility increases by warming and lowering the pH of the solution.

Each Adenoscan vial contains a sterile, non-pyrogenic solution of adenosine 3 mg/mL, and sodium chloride 9 mg/mL, in Water for Injection. The pH of the solution is between 4.5 and 13.

INDICATIONS AND USAGE:

Intravenous Adenoscan is indicated as an adjunct to thallum-201 myocardial perfusion imaging in patients unable to exercise adequately. (See WARNINGS.)

CONTRAINDICATIONS:

Intravenous Adenoscan (adenosine) should not be administered to individuals with:

1. Second or third degree AV block (except in patients with a functioning artificial pacemaker).
2. Sinus node disease, such as sick sinus syndrome or symptomatic bradycardia (except in patients with a functioning artificial pacemaker).
3. Known or suspected bronchospastic or bronchopulmonary lung disease (e.g., asthma).
4. Known hypersensitivity to adenosine.

WARNINGS:

Fetal Cardiac Arrest, Life Threatening Ventricular Arrhythmias, and Myocardial Infarction

Fetal cardiac arrest, sustained ventricular tachycardia (requiring resuscitation), and nonfatal myocardial infarction have been reported coincident with Adenoscan infusion. Patients without these events have been at risk.

Sinusoidal and Atrioventricular Block Model Block

Adenoscan (adenosine) acts directly depressant effect on the SA and AV nodes and has the potential to cause first-, second- or third-degree AV block, or sinus bradycardia. Approximately 8% of patients develop AV block with Adenoscan, including first-degree (2.8%), second-degree (2.2%) and third-degree (2.6%) heart block. AV block has been asymptomatic, transient, and did not require intervention. Adenoscan causes sinus bradycardia. Adenoscan should be used with caution in patients with pre-existing first-degree AV block or bundle branch block and should be avoided, however, in patients with high-grade AV block or sinus node dysfunction (except in patients with a functioning artificial pacemaker). Adenoscan should be discontinued in any patient who develops persistent or symptomatic high-grade AV block. Sinus pause has been rarely observed with adenosine infusion.

Hypotension

Adenoscan (adenosine) is a potent peripheral vasodilator and can cause significant hypotension. Patients with an intact baroreceptor reflex mechanism are able to maintain blood pressure and tissue perfusion in response to Adenoscan by increasing heart rate and cardiac output. However, Adenoscan should be used with caution in patients with autonomic dysfunction, stenotic valvular heart disease, pericardial or papillary muscle disease, certain arrhythmias, cardiac tamponade, or uncontrolled hypotension or bradycardia due to the risk of hypertensive complications in these patients. Adenoscan should be discontinued in any patient who develops persistent or symptomatic hypotension.

Hypersensitivity

Increases in systolic and diastolic pressure have been observed (as great as 140 mm Hg systolic in one case) coincident with Adenoscan infusion; most increases resolved spontaneously within several minutes, but in some cases, hypertension lasted for several hours.

Bronchoconstriction

Adenoscan (adenosine) is a respiratory stimulant (probably through actuation of carotid body chemoreceptors) and intravenous administration in man has been shown to result in increased ventilation (Ve) and reduce arterial Pco2 causing respiratory alkalosis. Approximately 28% of patients experience breathlessness (dyspnea) or an urge to breathe deeply with Adenoscan. These respiratory complaints are transient and only rarely require intervention. Adenoscan is contraindicated in patients who are known to be hyperventilated before administration or who have had previous reactions due to hyperventilation.

Drug Interactions

Intravenous Adenoscan (adenosine) has been given with other cardiovascular drugs (such as beta adrenergic blocking agents, calcium glycosides, and calcium channel blockers) without apparent adverse interactions, but its effectiveness with these agents has not been systematically evaluated. Because of the potential for additive or synergistic depressant effects on the SA and AV nodes, however, Adenoscan should be used with caution in the presence of these agents. The safety of Adenoscan in patients with heart disease or heart rhythm disturbances may be affected by concomitant use of other drugs including antiplatelet agents, sympathomimetic agents (e.g., ephedrine and phenylephrine), and calcium channel blockers.

Cardiovascular, Mutagenesis, Impairment of Fertility

Studies in animals have not been performed to evaluate the carcinogenic potential of Adenoscan (adenosine). Adenosine was negative for genotoxic potential in the Salmonella (Ames Test) and Mammalian Micronucleus Assay.

Pregnancy Category C

Animal reproduction studies have not been conducted with adenosine; nor has studies been performed in pregnant women. Because it is not known whether Adenoscan can cause fetal harm when administered to pregnant women, Adenoscan should be used during pregnancy only if clearly needed.

Pediatric Use

The safety and effectiveness of Adenoscan in patients less than 18 years of age have not been established.

ADVERSE REACTIONS:

The following reactions with an incidence of at least 1% were reported with intravenous Adenoscan among 11421 patients enrolled in controlled and uncontrolled U.S. clinical trials. Despite the short half-life of adenosine, 10.8% of the side effects occurred with no relationship to Adenoscan but occurred during several other hours. Also, 11.6% of the side effects that began coincident with the infusion persisted for up to 54 hours after the infusion was complete. In many cases, it is not possible to know whether these late adverse events are the result of Adenoscan infusion.

Flushing 44% Gastrointestinal discomfort 13% Second-degree AV block 3%
Chest discomfort 12% Upper extremity discomfort 12% Hypertension 3%
Dyspnea or urge to breathe deeply 29% Headache 27% Diastolic 18%
Headache 12% Lower extremities/drip 46% Hypertension 2%
Throat, neck or jaw discomfort 15% 1st-degree AV block 36% Arrhythmia 1%

Adverse experiences of any severity reported in less than 1% of patients include:

Body as a Whole: back discomfort, lower extremity discomfort, weakness.
Cardiovascular System: nonfatal myocardial infarction; life-threatening ventricular arrhythmias; third-degree AV block; bradycardia; palpitations; sinus arrest; sinus pause; hypotension.
Central Nervous System: dizziness; emotional instability; tremors.
Gastrointestinal System: epigastric; uneasiness; nausea.
Respiratory System: cough.
Special Senses: blurred vision; dry mouth; ear discomfort; metallic taste; nasal congestion; sore throat; tongue discomfort.

OVERDOSAGE:

The half-life of Adenoscan is less than 10 seconds and side effects of Adenoscan (when they occur) usually resolve quickly when the infusion is discontinued. Persistent effects have been observed with methacholine, as well as caffeine and theophylline. Theophylline and caffeine are competitive adenosine receptor antagonists and theophylline has been used to effectively terminate persistent side effects. In controlled U.S. clinical trials, theophylline (50-125 mg intravenous injection) was needed to abort Adenoscan side effects in less than 2% of patients.

DOSAGE AND ADMINISTRATION:

For Intravenous infusion only.

Adenoscan should be given as a continuous peripheral intravenous infusion.

The recommended intravenous dose for adults is 140 mcg/kg/min infused for at least 5 minutes (total dose of 0.84 mg/kg).

The rate of infusion of thallum-201 should be reconstituted at the midpoint of the Adenoscan infusion (i.e., after the first 3 minutes of Adenoscan. Thallum-201 Adenoscan must be reconstituted and added to the AV into the infusion). The reconstitution should be done in the venous access to prevent an inadvertent increase in the dose of Adenoscan (the balance of the IV tubing may be clamped). There are no data on the safety or efficacy of alternative Adenoscan administration protocols. The safety and efficacy of Adenoscan administration by the intravenous route have not been established.

Note: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

CAUTION:

Federal law prohibits dispensing without prescription.

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- Rapid and sustained myocardial uptake, with images available from 15 minutes to 4 hours post-injection
- Rapid GI clearance

A convenient view.
- Room temperature preparation, and 8 hour reconstituted shelf-life
- No redistribution
- Available in unit dose

An efficient view.
- Flexible scheduling
- Sensitive and reliable detection of coronary disease

A patient’s view.
- Low radiation exposure compared to other myocardial perfusion agents
- Less than 1% of patients experienced side effects in clinical trials of 764 adults
- Myoview is not indicated for use with pharmacologic stress agents

Please see brief summary of prescribing information on following page.
Pregnancy Category C
Animal reproduction studies have not been conducted with Myoview. It is not known whether Myoview can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Therefore, Myoview should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
Technetium Tc99m Pertechnetate can be excreted in human milk. Formula, should be substituted for breast milk until the technetium has cleared from the body of the nursing woman.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS
Adverse events were evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 26-94 years). The subjects received a mean dose of 7.67 mCi on the first injection and 22.4 mCi on the second injection of Myoview.

Deaths did not occur during the clinical study period of 2 days. Sudden cardiac deaths occurred 3 days to 6 months after injection and were thought to be related to the underlying disease or cardiac surgery. After Myoview injection, serious episodes of angina occurred in 3 patients. Overall cardiac adverse events occurred in 5764 (less than 1%) of patients after Myoview injection.

The following events were noted in less than 1% of patients:
Cardiovascular: angina, hypertension, Torsades de Pointes
Gastrointestinal: vomiting, abdominal discomfort
Hypersensitivity: cutaneous allergy, hypotension, dyspnea
Special Senses: metallic taste, burning of the mouth, smelling something

There was a low incidence (less than 4%) of a transient and clinically insignificant rise in white blood cell counts following administration of the agent.

Dosage and Administration

For exercise and rest imaging, Myoview is administered in two doses:

- The first dose of 5.8 mCi (185-296 MBq) is given at peak exercise.
- The second dose of 15-24 mCi (555-888 MBq) is given approximately 4 hours later, at rest.

Imaging may begin 15 minutes following administration of the agent.

Dose adjustment has not been established in renal or liver impaired, pediatric or geriatric patients.

Radiation Dosimetry

Based on human data, the absorbed radiation doses to an average human adult (70 kg) from intravenous injections of the agent under exercise and resting conditions are listed in Table 1. The values are listed in descending order as rad/MCi and mSv/MCi and assume urinary bladder emptying at 3.5 hours.

Table 1
Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

<table>
<thead>
<tr>
<th>Target Organ</th>
<th>Exercise (rad/MCi)</th>
<th>NuCi (mCi)</th>
<th>Rest (rad/MCi)</th>
<th>NUci (mCi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gall bladder wall</td>
<td>0.123</td>
<td>33.2</td>
<td>0.180</td>
<td>48.6</td>
</tr>
<tr>
<td>Upper large intestine</td>
<td>0.075</td>
<td>20.1</td>
<td>0.113</td>
<td>30.4</td>
</tr>
<tr>
<td>Bladder wall</td>
<td>0.058</td>
<td>15.6</td>
<td>0.071</td>
<td>19.3</td>
</tr>
<tr>
<td>Lower large intestine</td>
<td>0.057</td>
<td>15.3</td>
<td>0.082</td>
<td>22.2</td>
</tr>
<tr>
<td>Small intestine</td>
<td>0.045</td>
<td>12.1</td>
<td>0.063</td>
<td>17.0</td>
</tr>
<tr>
<td>Kidney</td>
<td>0.039</td>
<td>10.4</td>
<td>0.046</td>
<td>12.5</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>0.030</td>
<td>8.04</td>
<td>0.043</td>
<td>11.6</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.029</td>
<td>7.88</td>
<td>0.035</td>
<td>9.55</td>
</tr>
<tr>
<td>Uterus</td>
<td>0.027</td>
<td>7.34</td>
<td>0.031</td>
<td>8.36</td>
</tr>
<tr>
<td>Bone surface</td>
<td>0.023</td>
<td>6.23</td>
<td>0.021</td>
<td>5.54</td>
</tr>
<tr>
<td>Pancreas</td>
<td>0.019</td>
<td>5.00</td>
<td>0.018</td>
<td>4.98</td>
</tr>
<tr>
<td>Stomach</td>
<td>0.017</td>
<td>4.60</td>
<td>0.017</td>
<td>4.63</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.016</td>
<td>4.34</td>
<td>0.022</td>
<td>5.83</td>
</tr>
<tr>
<td>Adrenals</td>
<td>0.016</td>
<td>4.32</td>
<td>0.015</td>
<td>4.11</td>
</tr>
<tr>
<td>Heart wall</td>
<td>0.015</td>
<td>4.14</td>
<td>0.015</td>
<td>3.93</td>
</tr>
<tr>
<td>Red marrow</td>
<td>0.015</td>
<td>4.14</td>
<td>0.015</td>
<td>3.97</td>
</tr>
<tr>
<td>Spleen</td>
<td>0.015</td>
<td>4.12</td>
<td>0.014</td>
<td>3.82</td>
</tr>
<tr>
<td>Muscles</td>
<td>0.013</td>
<td>3.52</td>
<td>0.012</td>
<td>3.32</td>
</tr>
<tr>
<td>Testes</td>
<td>0.013</td>
<td>3.41</td>
<td>0.011</td>
<td>3.05</td>
</tr>
<tr>
<td>Liver</td>
<td>0.012</td>
<td>3.22</td>
<td>0.012</td>
<td>3.15</td>
</tr>
<tr>
<td>Thymus</td>
<td>0.012</td>
<td>3.11</td>
<td>0.009</td>
<td>2.54</td>
</tr>
<tr>
<td>Brain</td>
<td>0.010</td>
<td>2.72</td>
<td>0.008</td>
<td>2.15</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.008</td>
<td>2.27</td>
<td>0.008</td>
<td>2.08</td>
</tr>
<tr>
<td>Skin</td>
<td>0.006</td>
<td>2.22</td>
<td>0.007</td>
<td>1.91</td>
</tr>
<tr>
<td>Breasts</td>
<td>0.006</td>
<td>2.22</td>
<td>0.007</td>
<td>1.83</td>
</tr>
</tbody>
</table>

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No.1 rev.). Society of Nuclear Medicine, 1976. Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4), 1986) and gave values of 8.61 x 10^4 mSv/MCi and 1.12 x 10^4 mSv/MCi after exercise and rest respectively.

Manufactured by Amersham International plc – Amersham, United Kingdom
Patent No. 5,045,302 (f)

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46th Annual Meeting

LOS ANGELES, CALIFORNIA

June 6-10, 1999

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Society of Nuclear Medicine
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Reston, VA 20190
Phone: (703) 708-9000 x229
Fax: (703) 709-9274
www.snm.org

LOCATION:
Los Angeles Convention Center
1201 South Figueroa Street
Los Angeles, CA 90015

DEADLINES:
Pre-Registration Ends: April 29, 1999
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Abstract Submission Deadline: January 8, 1999

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Categoricals

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2. Fax-On-Demand*, starting January
3. The Journal of Nuclear Medicine, February Issue
4. The Journal of Nuclear Medicine Technology, March Issue

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   USA
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Call for Abstracts of Scientific Papers and Computer Exhibits

The Society of Nuclear Medicine 46th Annual Meeting June 6-10, 1999 Los Angeles, California

The 1999 Scientific Program Committee and the Scientific & Teaching Committee solicit the submission of abstracts from members and non-members of the Society of Nuclear Medicine for the 46th Annual Meeting in Los Angeles, California. Accepted Scientific Paper and Computer Exhibit abstracts will be published in a special supplement to the May issue of The Journal of Nuclear Medicine (JNM) and accepted Technologist Section abstracts will be published in the June issue of the Journal of Nuclear Medicine Technology (JNMT). Original contributions on a variety of topics related to nuclear medicine will be considered, including:

For Society Abstracts:
- Basic Science/Clinical Applications
- Cardiology
- Neurosciences
- General Clinical Specialties
- Oncology/Hematology
- Instrumentation and Data Analysis
- Radiopharmaceutical Chemistry
(In total, 29 Society abstract categories are offered)

For Technologist Abstracts:
- Topics similar to Society topics listed above, but 16 specifically tailored for the Technologist Section
(In total, 16 Technologist abstract categories are offered)

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

Deadline for receipt of abstracts for Scientific Papers and Computer Exhibits is Friday, January 8, 1999.

This year, SNM will be utilizing an electronic abstract processing system developed by Medical Support Services (MSS), a company with several years of experience in developing abstract processing systems for medical organizations.

Please use one of the following methods to acquire the free software to submit your abstract:
1. Download the PC or Macintosh version of the SNM Abstract Submitter Assistant from the SNM Web Site at www.snm.org under Meetings.
2. Request a copy of the SNM Abstract Submitter Assistant directly from MSS at the following address: Attn: Submitter Assistant Request, Society of Nuclear Medicine, 1000 Massachusetts Avenue, 3rd Floor, Cambridge, MA 02138-5304 USA. Indicate your preference for PC or Macintosh.
Paul C. Aebersold Award

Applications are invited for the 1999 Paul C. Aebersold Award for outstanding achievement in basic science applied to Nuclear Medicine. This award commemorates the contributions of Dr. Paul Clarence Aebersold to the applications of nuclear physics to Nuclear Medicine and radiation biology, as well as his contributions to the Society of Nuclear Medicine (SNM). Dr. Aebersold contributed greatly to the emergence of Nuclear Medicine as a discipline by his energetic leadership in the provision of cyclotron-generated and reactor-produced radionuclides, and by his numerous publications and lectures. In giving this award, the Society thus symbolically signifies its appreciation of the warm and vital person who became the Society's first Honorary Member.

Nominations should be supported by the nominee’s curriculum vitae and at least two letters supporting the nomination. These letters should briefly describe the contributions in basic science for which the nominee is proposed. The nominee does not need to be a SNM member.

Nominations deadline: December 31, 1998. Please submit nominations and supporting documents to William J. MacIntyre, Ph.D., c/o Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, Virginia 20190-5316.
One of the goals of the Society of Nuclear Medicine Technologist Section (SNM-TS) has been to take an active role in educating the public and the medical community about nuclear medicine procedures and the benefits of this functional imaging modality.

This is the official entry form for the 1998 PR Stars Contest Sponsored by the SNM-TS and Capintec, Inc. Please fill out the entry form and complete the requested information on the reverse side. Based on the information you provide, a panel of judges will evaluate the entries using the point system outlined on the next page and select a winner. All entrants must be a Nuclear Medicine Technologist and a staff member of a hospital or nuclear medicine facility. Entries must be post-marked by December 1, 1998.

NEW PRIZES
Thanks to the generous support of the 1998 PR Stars corporate sponsor, Capintec, Inc.
1st Place: $800 for the individual and $600 for the institution. Up to $850 in airfare to the 1999 SNM Annual Meeting in Los Angeles to receive your prize! Payment of your pre-registration fee to attend the 1999 SNM Annual Meeting. Your SNM-TS membership dues paid for one year.
2nd Place: $600 for the individual and $400 for the institution. Up to $650 in airfare to the 1999 SNM Annual Meeting in Los Angeles to receive your prize! Payment of your pre-registration fee to attend the 1999 SNM Annual Meeting. Your SNM-TS membership dues paid for one year.
3rd Place: $550 for the individual and $350 for the institution. Up to $650 in airfare to the 1999 SNM Annual Meeting in Los Angeles to receive your prize! Payment of your pre-registration fee to attend the 1999 SNM Annual Meeting. Your SNM-TS membership dues paid for one year.
4th-10th Place: Your SNM-TS membership dues paid for one year.

ENTRY FORM
Your Name: ________________________________
Hospital/Facility: __________________________
Address: __________________________________
City: __________________ State: _______ Zip: _______
Telephone: __________________ Fax: __________

Mail your entry information (including this completed form) by December 1, 1998 to:
Society of Nuclear Medicine
1998 PR Stars Contest
1850 Samuel Morse Drive
Reston, VA 20190
Fax: 703-708-9018
Telephone: 703-708-9000

Please complete reverse side
Please describe and document your promotional activities and results. The following point system will be used for judging.

1. Please compose a detailed description, including the goals and objectives, of your nuclear medicine PR activities. (7 points)

2. Did the goals and objectives you set reflect those of the PR Stars Contest to:
   a. Reinforce nuclear medicine to referring physicians? (10 points)
   b. Promote nuclear medicine to healthcare workers? (5 points)
   c. Increase community awareness? (5 points)
   d. Encourage career paths? (5 points)

3. How effective were you in reaching the goals of the PR Stars Contest?
   a. Increasing physician referrals? (10 point)
   b. Increasing awareness among healthcare workers? (5 points)
   c. Increasing community awareness? (5 points)
   d. Encouraging career paths? (5 points)
   e. Showing pride in your profession. (5 points)

4. What resources did you have available to you and how effectively did you use them? (budget, manpower, media, etc...) (13 points)

5. Can your program be used easily by others? Please explain (5 points)

6. Was your program cost effective? Please explain (5 points)

7. When did your nuclear medicine PR activity take place? (no points)

Please provide a detailed time-line of the planning and implementation of your program. (10 points)
For example: March 10 Strategic planning session with staff technologists
May 1 Drafted nuclear medicine article for facility newsletter

8. Are you currently an active member of the SNM-TS? (5 points)
   □ Yes □ No

Thank you for your entry! Good Luck!

Val Cronin, CNMT
1997 - 1998 Nuclear Medicine Week Chairperson

Susan Gavel, CNMT
1998 - 1999 Nuclear Medicine Week Chairperson
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- Record-Keeping
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- NRC Inspections
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Katherine M. Elliott
Alisha C. Mitro
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June 6-10, 1999
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PREP will enable you to easily provide important information to your patients — promoting confidence and an understanding of their nuclear medicine procedure. Help to establish nuclear medicine as an integral part of patient care by giving referring physicians the PREP information.

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The Society of Nuclear Medicine's Medical Internal Radiation Dose Committee serves as the international clearinghouse for data concerning the use of radionuclides in humans. Like the MIRD Primer and Radionuclide Data and Decay Schemes, the new MIRD Cellular S Values promises to become a standard reference publication within all diagnostic imaging centers.

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CRITICAL QUESTIONS

When no lesion can be detected in a nuclear scan of the breast...

1) Is there no lesion? - or

2) Is there a lesion that cannot be detected?

A lesion modeled in a geometric phantom has a lower limit of detectability than would be found in vivo. The same modeling with a realistic phantom has a higher limit detectability.

The results of a study by Doshi et al., compared the detectability of lesions on a PET scan between the types of geometric phantoms that are commonly used and the RSD Heart/Thorax Phantom. There was a 65% decrease in signal-to-noise ratio with the RSD phantom due to expanding the simulation from lesions-plus-breasts that contain activity, to lesions-plus-breasts-plus thorax, all containing activity. This was “due to the effects of increased scatter and attenuation”. There was also a 23% decrease in contrast in the RSD phantom, due to surrounding activity from nearby organs such as the heart.

The RSD Heart/Thorax Phantom has a heart with 3 standard or custom defects, perfusable lungs, a liver, a chest overlay to represent adipose tissue, and breasts to fit either the thorax or the chest overlay. Each organ will accept a graded series of fillable tumors. The organs and the thoracic cavity are also fillable with active solutions. This phantom is directed not only to PET and SPECT, but also to MRI, when filled with a copper sulfate solution.

RSD offers a striatal phantom that similarly increases the validity of scans of the right and left nucleus caudate and the right and left putamen.

RSNA Booth #2551.

Positions Needed

Tenure-Track Faculty Position in Neuroscience Imaging

The Center for Advanced Imaging at West Virginia University is seeking to fill a tenure track position in the Department of Radiology for a scientist (MD and/or PhD) who studies sensory or language processing utilizing MRI and/or PET. The Center houses state-of-the-art research equipment, including a GE Sigma 1.5T MR Imager, a GE Advance PET Scanner and a radiocchemistry-cyclotron facility. In addition, research collaborations with the nearby National Institute of Occupational Safety and Health allows access to a new small bore 300 MHz NMR imaging system. The successful candidate will be encouraged to further develop this specialty throughout our large, diversified practice. We are situated in the beautiful Finger Lakes region of upstate New York with many recreational, cultural and educational opportunities available. Please reply to Steven Herbert, MD, Department of Radiology, The Genesee Hospital, 224 Alexander St., Rochester, NY 14607.

Assistant Attending in Nuclear Medicine

Memorial Sloan-Kettering Cancer Center is seeking a Board Certified Nuclear Medicine Physician for a position as Assistant Attending in Nuclear Medicine. The individual should have at least 3 years experience in Clinical Nuclear Medicine, demonstrated experience of scholarly pursuits of clinical problems, and a commitment to teaching. PET experience is highly desirable. Memorial Sloan-Kettering Cancer Center is an equal opportunity employer. Please send inquiries to Steven M. Larson, MD, Chief, Nuclear Medicine Service, Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, New York, NY 10021.

Licensed Radiopharmacist Needed

Licensed Radiopharmacist needed to oversee antibody radio-labeling laboratory within Memorial Sloan-Kettering Cancer Center. Please contact Steven M. Larson, MD, at 212-639-7373.

Nuclear Medicine Technologist

Provena Covenant Medical Center is seeking a Nuclear Medicine Technologist to work in our Medical Imaging department. This full-time position will work Monday-Friday with rotating call. Candidates must be registered or registry eligible in Nuclear Medicine Technology and be licensed in Illinois. We offer an excellent benefits package that includes options in health care, dental, vision, life and long-term disability insurances. Qualified candidates are encouraged to contact Human Resources, Provena Covenant Medical Center, 1400 West Park St., Urbana, IL 61801. Phone: (217) 337-2224. Fax: (217) 337-2619. http://www.covenant-cau.com. EOE.

Pediatric Nuclear Medicine Specialist—Québec

The McGill University Health Centre (MUHC) invites applications for a full-time staff appointment in Pediatric Nuclear Medicine located in the Montréal Children’s Hospital. Included with this appointment is an appropriate academic rank within the University, Department of Medical Imaging, subject to the approval of the Professor and Chairman. The candidate must be experienced in Pediatric Nuclear Medicine subsequent to a formal fellowship training program. An interest in teaching and research activities within the specialty is necessary. Furthermore, qualifications should include eligibility for licensing by the Collége des médecins du Québec and certification in Nuclear Medicine from the Collège des médecins du Québec. In accordance with Canadian immigration requirements, priority will be given to Canadian citizens and permanent residents of Canada. McGill University is committed to equity in employment. Applicants should apply by January 9, 1999 to Dr. A.M. O’Gorman, Director, Department of Medical Imaging, The Montréal Children’s Hospital, 2300 Tupper St., Rm. C-309, Montréal Québec, H3H 1P3 Canada. Phone: (514) 934-4450. Fax: (514) 934-4347. Email: aogom@mcgill.ca.

Faculty Position

Assistant/Associate Professor, Pharmacy Practice (Radiopharmacy) and Coordinator of Radiopharmacy Education

College of Pharmacy

University of New Mexico Health Sciences Center

The College of Pharmacy at the University of New Mexico (UNM) Health Sciences Center has a 12-month, tenure track, assistant/associate professor position currently available within its Pharmacy Practice faculty. Starting date is negotiable.

Minimum qualifications include either an M.S. in Pharmaceutical Sciences with emphasis in Radiopharmacy, or Pharm.D. or Ph.D. degree and at least five years practice experience in nuclear pharmacy, and a record of scholarship. Desirable qualifications include a residency or fellowship in radiopharmacy, documented research in radiopharmaceutical sciences and pharmacy practice, teaching experience, board certification in nuclear pharmacy (BCNP) by the Board of Pharmaceutical Specialties, demonstrated ability to advise and direct professional and graduate student research, eligibility for licensure as a pharmacist in New Mexico and a record demonstrating the ability to collaborate. The successful applicant will participate in both didactic and experiential teaching, develop and implement training programs for nuclear pharmacy specialists, and establish a program of scholarship at the College of Pharmacy. The position offers excellent opportunities for collaborative scholarship with faculty members of the UNM Health Sciences Center.

For best consideration, applications should be received by January 15, 1999; however, applications will be accepted until the position is filled.

Applicants should send a letter of interest specifically addressing the minimum and desirable qualifications, curriculum vitae, and the names, addresses and telephone numbers of three references to:

Scott W. Burchiel, Ph.D.
College of Pharmacy
University of New Mexico Health Sciences Center
2502 Marble NE
Albuquerque, NM 87131-5691
Phone: (505) 272-0920 • Fax: (505) 272-6749

The University of New Mexico is an Equal Opportunity and Affirmative Action Employer.

Cedars-Sinai Medical Center

Nuclear Medicine Residency

Cedars-Sinai Medical Center, a 1000 bed, full service, acute, tertiary care hospital affiliated with UCLA School of Medicine, is seeking two residents for our ACGME approved program in Nuclear Medicine. Our dynamic department includes 6 multi-detector SPECT systems, 4 single detector systems and 3 multi-crystal cameras, and a PET Scanner. In addition, we offer a full range of nuclear medicine services.

Staffing includes 4 nuclear medicine physicians, a radiopharmacist and 2 physicists. The program emphasizes teaching, research, and a diversified clinical experience. Major research programs exist in nuclear cardiology, nuclear oncology, as well as, pulmonary and endocrine medicine. If you enjoy working in a busy, progressive environment with a challenge for personal growth, please contact:

Daniel S. Berman, M.D.
Director, Nuclear Medicine Residency Program
C/O Michael M. Catron
Imaging Housestaff Coordinator
Cedars-Sinai Medical Center
8700 Beverly Boulevard, Room 5416
Los Angeles, California 90048

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The new, third edition of the widely popular SPECT: A Primer is now available from Matthews Medical Books at the toll-free number below.

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The new SPECT Primer features an enhanced section on Clinical Applications, incorporating the latest and most widely accepted fundamental knowledge in the field, with, three all-new chapters on Acquisition Devices, Processing Devices, and Clinical Indications. And in every chapter, you’ll find expanded material to help nuclear medicine professionals who use SPECT perform at peak.

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The new SPECT Primer and the new Review of Nuclear Medicine Technology will be on sale at the SNM Publications Booth during the Annual Meeting in Denver.
The first imaging modality to target acute DVT

AcuTect—a new, unique, radiolabeled synthetic peptide—is the first to offer you the ability to clearly, safely, and comfortably target acute clots. AcuTect is indicated for scintigraphic imaging of acute venous thrombosis in the lower extremities of patients who have signs and symptoms of acute venous thrombosis. AcuTect binds preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets. AcuTect appears to detect acute and not chronic venous thrombosis. This is based on in vivo and ex vivo animal data; not confirmed clinically. The result is a new sensitivity that challenges venography—the “gold standard.”

More than just another diagnostic option—AcuTect is designed for a more confident course of treatment in a potentially life-threatening condition.

Clinical follow-up studies of patients with negative AcuTect scans have not been performed to determine if negative image findings mean the absence of acute venous thrombosis. If a patient has clinical signs and symptoms of acute venous thrombosis, a clinical management decision to withhold treatment with anticoagulants should not be based on a negative AcuTect study alone.

After administration of AcuTect, as with the administration of other intravenous drugs, patients with a history of drug reactions, other allergies, or immune system disorders should be observed for several hours.

For customer service, call 1-877-DIATIDE.

The difference is acute.

Diatide, Inc.

Please see brief summary of prescribing information on following page.

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ADVERSE REACTIONS

Adverse events were evaluated in clinical studies of 642 adults who received technetium Tc 99m 20.0 mCi labeled to approximately 70 - 100 mCi of biphasicide. Of these adults, 40% were women and 56% men. The mean age was 53.7 years (17 to 95 years). In all patients, adverse events were monitored for at least 3 hours. In a subset of 168 patients, adverse events were monitored for 24 hours. Deaths did not occur during the clinical study period. Following injection of technetium Tc 99m, a serious episode of hypotension occurred in one patient who had acute hypotension that began within 10 minutes of injection and, after 60 minutes, progressed to a systolic pressure of 70 mm Hg. At least one adverse event occurred in 26/642 (4.1%) of patients after technetium Tc 99m injection. Pain was the most commonly reported adverse event (1.7% of patients or healthy volunteers). Table 1 lists adverse events reported in 0.9% or more of patients who received technetium Tc 99m injection.

**Table 1: Adverse Events Reported in ≥0.9% of Patients Following AcuTect™ Injection in Clinical Studies**

<table>
<thead>
<tr>
<th>Number of Patients Exposed to AcuTect™</th>
<th>Number of Patients with at Least One Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>642</td>
<td>29 (4.5%)</td>
</tr>
<tr>
<td>Body as a Whole</td>
<td>21 (3.2%)</td>
</tr>
<tr>
<td>Back, leg, chest</td>
<td>13 (2.0%)</td>
</tr>
<tr>
<td>Headache</td>
<td>10 (1.6%)</td>
</tr>
<tr>
<td>Cardiovascular System</td>
<td>13 (2.0%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>5 (0.8%)</td>
</tr>
<tr>
<td>Hypothermia</td>
<td>3 (0.5%)</td>
</tr>
</tbody>
</table>

Other adverse events which occurred in ≤0.5% of patients following receipt of AcuTect™ included: agitation, asthma, bradycardia, cardiovascular disorder, chills, convulsions, dizziness, fever, hypotension, injection site reaction, liver enzyme elevation, nausea, paresthesia, pruritus, sweat, tachycardia, twitch, urticaria, and vomiting.

OVERDOSAGE: Clinical consequences of overdosage with technetium Tc 99m have not been studied.

**DOSAGE AND ADMINISTRATION:** To detect acute venous thrombosis in a lower extremity, reconstrued AcuTect™ should be administered as a peripheral intravenous injection in an upper extremity, at a dose of approximately 100 µCi of biphasicide radiolabeled with 37 mCi technetium Tc 99m. Technetium Tc 99m biphasicide should be drawn into the syringe and administered using sterile technique. If nondisposable equipment is used, scopolamine care should be taken to prevent residual contamination with traces of cleaning agents. Unused portions of the drug must be discarded appropriately. (See Instructions for Preparation Section of Full Product Information.)

**Lower Extremity Imaging**

AcuTect™ imaging should begin between 10 and 60 minutes after injection. Patients should void just before imaging in order to limit the influence of urinary bladder radioactivity since technetium Tc 99m is cleared from the blood by the kidney. If it is determined that imaging needs to be repeated, additional images may be obtained up to three hours without repositioning. The safety of more than one dose has not been studied.

Positive AcuTect™ uptake in the deep venous structures is defined as asymmetrical vascular uptake (with or without superimposed diffuse uptake) in contrast enhanced images, and asymmetry in both anterior and posterior projections. If asymmetry applies only after extreme contrast enhancement, then diffuse asymmetry must also be present for scoring an image as positive. Superficial increased uptake is not to be interpreted as acute deep venous thrombosis.

**RADIATION DOSIMETRY**

Based on human data, the absorbed radiation doses to an average adult (70 kg) from an intravenous injection of technetium Tc 99m are listed in Table 2. The values are listed in descending order as mSv/mCi and mGy/MBq and assume urinary bladder evacuation after 4.8 hours.

**Table 2: Radiation Absorbed Doses for a 70kg Adult**

<table>
<thead>
<tr>
<th>Target Organ</th>
<th>mSv/mCi</th>
<th>mGy/MBq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary Bladder Wall</td>
<td>0.275</td>
<td>5.089</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.190</td>
<td>0.514</td>
</tr>
<tr>
<td>Lower Urinary Tract</td>
<td>0.029</td>
<td>0.514</td>
</tr>
<tr>
<td>Lower Leg</td>
<td>0.017</td>
<td>0.051</td>
</tr>
<tr>
<td>Chest</td>
<td>0.032</td>
<td>0.125</td>
</tr>
<tr>
<td>Thyroid Gland</td>
<td>0.020</td>
<td>0.049</td>
</tr>
<tr>
<td>Testes/Ovaries</td>
<td>0.020/0.230</td>
<td>0.035/0.063</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.016</td>
<td>0.045</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.009</td>
<td>0.025</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>0.0055</td>
<td>0.016</td>
</tr>
</tbody>
</table>

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1, rev. Soc. Nucl. Med., 1976). Effective dose equivalent was calculated in accordance with ICRP 53 (Ann. ICRP 14, 1.9, 1988) and gave a value of 0.039/0.005/0.004 mSv/mCi (0.035/0.005/0.004 mGy/MBq).

**HOW SUPPLIED**

Each kit contains one vial containing a sterile, nonpyrogenic, freeze-dried mixture of biphasicide, stannous chloride dihydrate and sodium glucoheptonate dihydrate, together with a package insert and adverse event reporting cards. Kits are available in packs of 5 vials.

**Storage**

Store the kit in a refrigerator at 2 to 8°C (36 to 46°F). The reconstructed injection solution at 20 to 25°C (68 to 77°F), using appropriate radiation shielding, for up to 6 hours.

The kit should be protected from light.

**Rx only**

Diatide, Inc.

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**References:**

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