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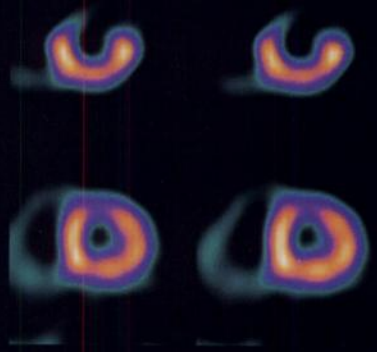

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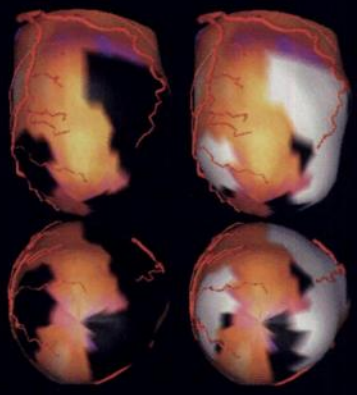
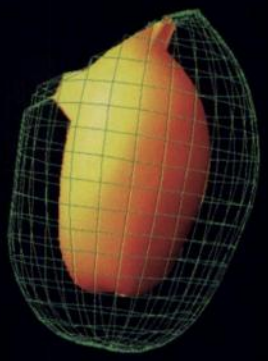


Emory Cardiac Toolbox



Cedars Gated SPECT Quantification

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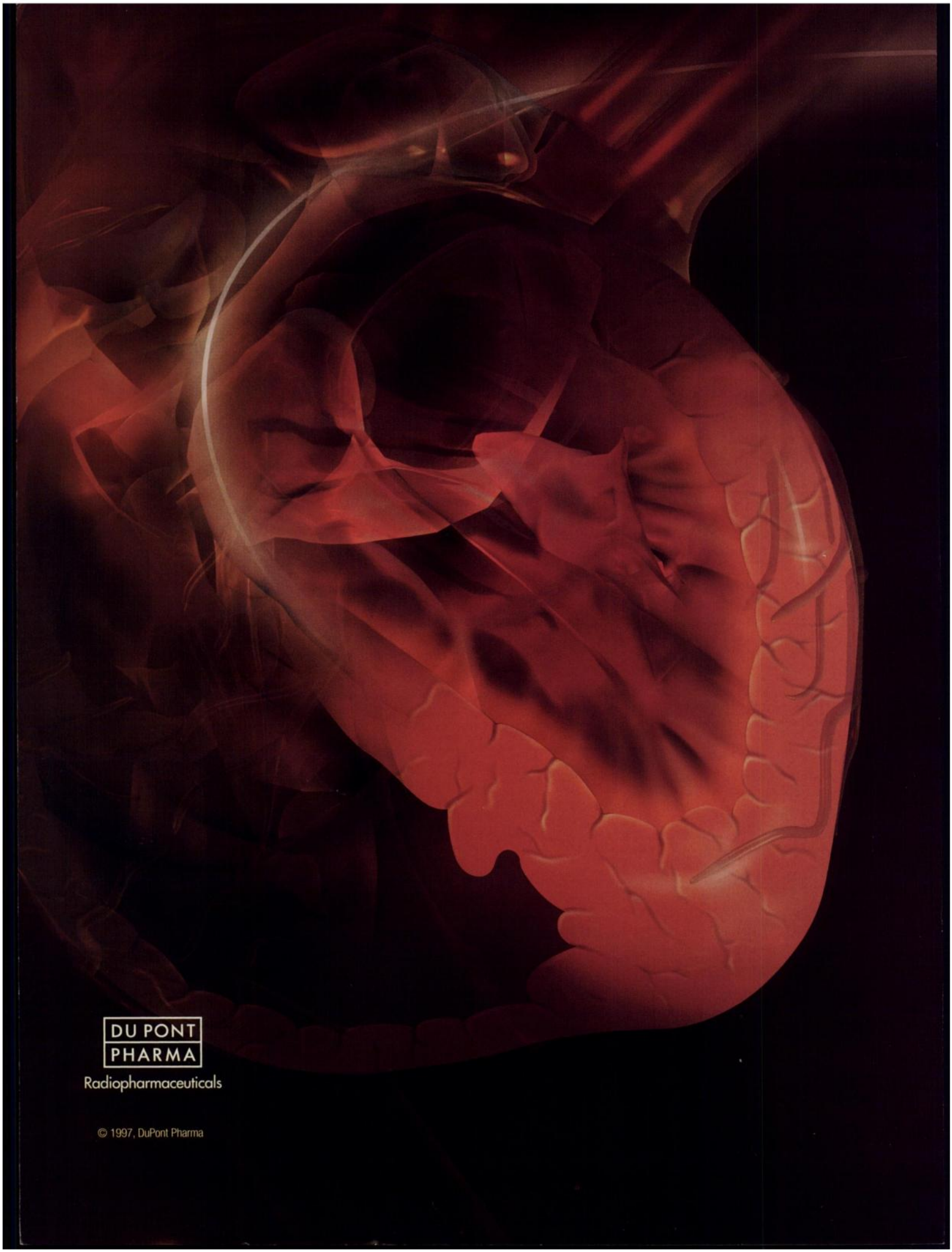

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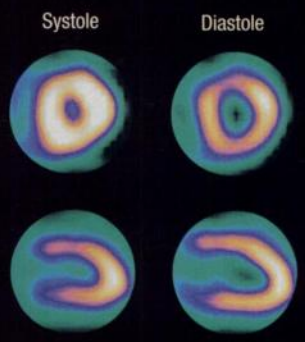


LVEF=51%

Gated SPECT images with CARDIOLITE®

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**

# Brief Summary

# Cardiolite®

## Kit for the preparation of Technetium Tc99m Sestamibi

**F O R  D I A G N O S T I C  U S E**

**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 safe, accepted clinical procedure. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (See PRECAUTIONS).

Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, arrhythmias, hypotension, bronchoconstriction 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 preparative 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 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.

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.

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 | 1% |

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5rads/30mCi at rest, 1.2 rads/30mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, $[Cu(MIBI)_4]BF_4$, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all *in vitro*). At cytotoxic concentrations (≥ 20μg/ml), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $[Cu(MIBI)_4]BF_4$ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/kg, > 600 × 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.

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 parosmia 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, dyspepsia, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, and hypotension also have been attributed 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 seizure occurring shortly after administration of the agent; transient arthritis in a wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthenia and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

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

370-1110MBq (10-30mCi)

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).

The patient dose should be measured by a suitable radioactivity 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 15-25°C before and after reconstitution.

**RADIATION DOSIMETRY:** The radiation doses to organs and tissues of an average patient (70kg) per 1110MBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

**Table 4. Radiation Absorbed Doses from Tc99m Sestamibi**

| | Estimated Radiation Absorbed Dose | | | |
|---|---|---|---|---|
| | REST | | | |
| | 2.0 hour void | | 4.8 hour void | |
| Organ | rads/ 30mCi | mGy/ 1110MBq | rads/ 30mCi | mGy/ 1110MBq |
| Breasts | 0.2 | 2.0 | 0.2 | 1.9 |
| Gallbladder Wall | 2.0 | 20.0 | 2.0 | 20.0 |
| Small Intestine | 3.0 | 30.0 | 3.0 | 30.0 |
| Upper Large Intestine Wall | 5.4 | 55.5 | 5.4 | 55.5 |
| Lower Large Intestine Wall | 3.9 | 40.0 | 4.2 | 41.1 |
| Stomach Wall | 0.6 | 6.1 | 0.6 | 5.8 |
| Heart Wall | 0.5 | 5.1 | 0.5 | 4.9 |
| Kidneys | 2.0 | 20.0 | 2.0 | 20.0 |
| Liver | 0.6 | 5.8 | 0.6 | 5.7 |
| Lungs | 0.3 | 2.8 | 0.3 | 2.7 |
| Bone Surfaces | 0.7 | 6.8 | 0.7 | 6.4 |
| Thyroid | 0.7 | 7.0 | 0.7 | 6.8 |
| Ovaries | 1.5 | 15.5 | 1.6 | 15.5 |
| Testes | 0.3 | 3.4 | 0.4 | 3.9 |
| Red Marrow | 0.5 | 5.1 | 0.5 | 5.0 |
| Urinary Bladder Wall | 2.0 | 20.0 | 4.2 | 41.1 |
| Total Body | 0.5 | 4.8 | 0.5 | 4.8 |
| | STRESS | | | |
| | 2.0 hour void | | 4.8 hour void | |
| Organ | rads/ 30mCi | mGy/ 1110MBq | rads/ 30mCi | mGy/ 1110MBq |
| Breasts | 0.2 | 2.0 | 0.2 | 1.8 |
| Gallbladder Wall | 2.8 | 28.9 | 2.8 | 27.8 |
| Small Intestine | 2.4 | 24.4 | 2.4 | 24.4 |
| Upper Large Intestine Wall | 4.5 | 44.4 | 4.5 | 44.4 |
| Lower Large Intestine Wall | 3.3 | 32.2 | 3.3 | 32.2 |
| Stomach Wall | 0.5 | 5.3 | 0.5 | 5.2 |
| Heart Wall | 0.5 | 5.6 | 0.5 | 5.3 |
| Kidneys | 1.7 | 16.7 | 1.7 | 16.7 |
| Liver | 0.4 | 4.2 | 0.4 | 4.1 |
| Lungs | 0.3 | 2.6 | 0.2 | 2.4 |
| Bone Surfaces | 0.6 | 6.2 | 0.6 | 6.0 |
| Thyroid | 0.3 | 2.7 | 0.2 | 2.4 |
| Ovaries | 1.2 | 12.2 | 1.3 | 13.3 |
| Testes | 0.3 | 3.1 | 0.3 | 3.4 |
| Red Marrow | 0.5 | 4.6 | 0.5 | 4.4 |
| Urinary Bladder Wall | 1.5 | 15.5 | 3.0 | 30.0 |
| Total Body | 0.4 | 4.2 | 0.4 | 4.2 |

Radiopharmaceutical Internal Dose Information Center, July, 1990, Oak Ridge Associated Universities, P.O. Box 117, Oak Ridge, TN 37831, (615) 576-3449.

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

Prior to lyophilization the pH is between 5.3-5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at 15-25°C before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each five (5) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each thirty (30) vial kit are one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material pursuant to section 35.11 and section 35.200 of Title 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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Radiopharmaceuticals

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All other business: 800-362-2668
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513121-0296 2/96

Printed in U.S.A.

**REFERENCES:** 1. Nichols K, DePuey EG, Rozanski A. Automation of gated tomographic left ventricular ejection fraction. *J Nucl Cardiol.* 1996;3:475-482. 2. Chua T, Kiat H, Germano G, et al. Gated technetium-99m sestamibi for simultaneous assessment of stress myocardial perfusion, post-exercise regional ventricular function and myocardial viability. *J Am Coll Cardiol.* 1994;23:1107-1114. 3. Stratmann HG, Williams GA, Wittry MD, et al. Exercise technetium-99m sestamibi tomography for cardiac risk stratification of patients with stable chest pain. *Circulation.* 1994;89:615-622. 4. Berman DS, Hachamovitch R, Kiat H, et al. Incremental value of prognostic testing in patients with known or suspected ischemic heart disease: a basis for optimal utilization of exercise technetium-99m sestamibi myocardial perfusion single-photon emission computed tomography. *J Am Coll Cardiol.* 1995;26:639-647. 5. Hachamovitch R, Berman DS, Kiat H, et al. Exercise myocardial perfusion SPECT in patients without known coronary artery disease. *Circulation.* 1996;93:905-914.

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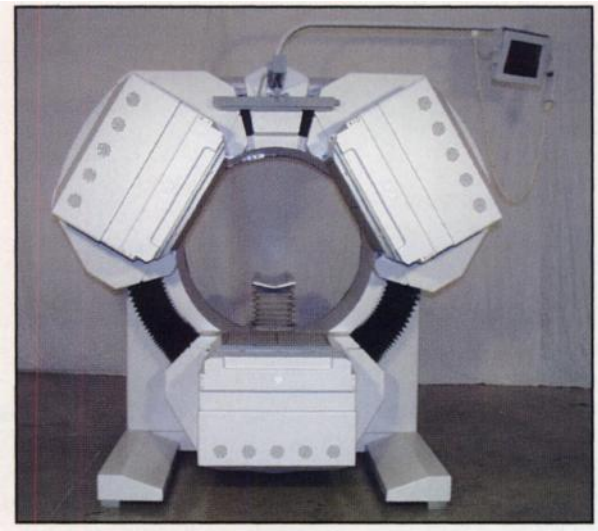
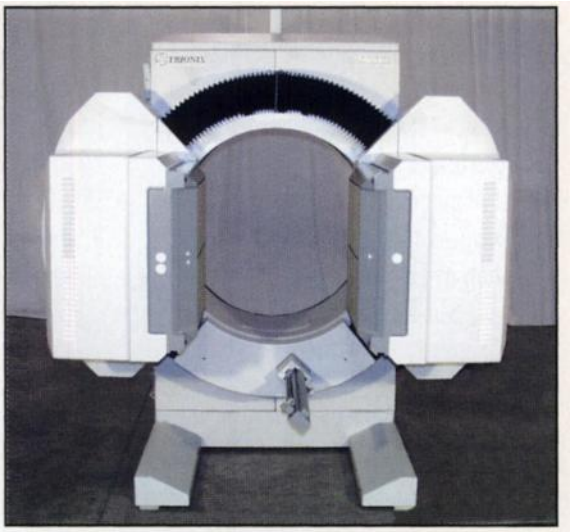
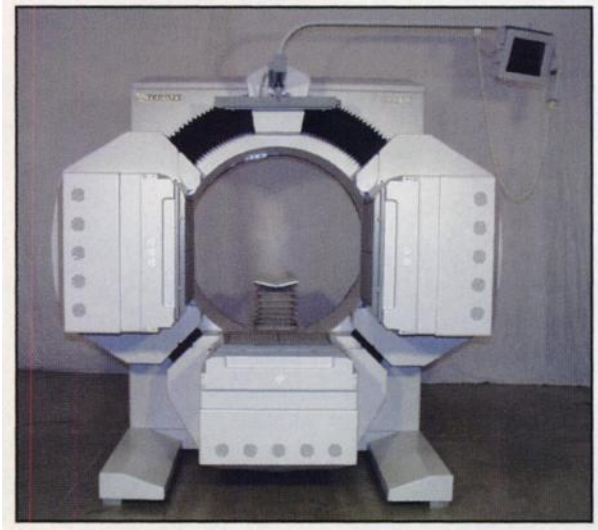
*TRIONIX* XLT Innovations

# Triad/Biad Arc

## XLT to Arc ☞ FDG ☞ QuaSAR ☞ Ultra







| **Technology:** | **Benefit:** |
|---|---|
| • **Arc Motion** | - Data Acquisition Versatility (Triad/Biad Mode) |
| • **FDG SPECT DISA** | - Simultaneous Metabolism/Perfusion Studies |
| • **QuaSAR SPECT** | - Improved Image Resolution/Quantitation |
| • **Ultra Computing** | - Speed, 3D Graphics, Multi-Media |

# FDG/MIBI DISA

## Dual Isotope Simultaneous Acquisition

### 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.
- Acquistion of Extrinsic Flood Correction tables for 511 keV Collimator: Simultaneous for Tc-99m and F-18 in one flood pool source.

### BASIC PERFORMANCE: TRIAD

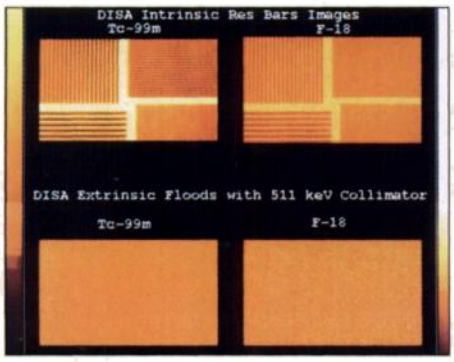
Intrinsic Energy Resolution for 511keV: 8.96 %

Intrinsic Spatial Resolution for 511keV:

| | UFOV | CFOV |
|---|---|---|
| FWHM | 1.92mm | 1.87mm |
| FWTM | 3.95mm | 3.86mm |

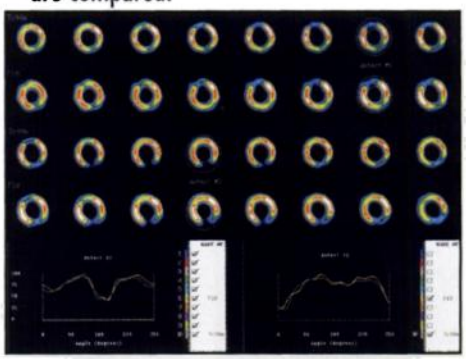
| Energy Window (%) | | Planar Sensitivity per Detector Head (cpm/μCi) | | Planar Resolution (mm) | | Reconstructed Spatial Resolution (mm) | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Tc-99m | | F-18 | |
| Tc-99m | F-18 | Tc-99m | F-18 | Tc-99m | F-18 | FWHM | FWTM | FWHM | FWTM |
| 20 | 15 | 65 | 52 | 6.6 | 8.2 | 9.3 | 18.0 | 10.7 | 21.5 |

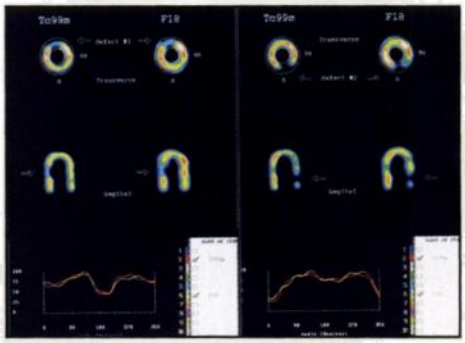
- Planar Spatial Resolution: Measured at 10 cm distance from collimator
- SPECT Spatial Resolution: Measured from a line source in the center of 22 cm dia. cylinder filled with water; 13 cm radius circular orbit;Recon Filter at Nyquist Frequency with pixel = 3.56mm




### CARDIAC PHANTOM TEST RESULTS:

- Simultaneous Acq. of Data Spectrum Cardiac Phantom with 300μCi 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. Drane'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.*
2. *Drane WE, Abbott FD, Nicole MW, Mastin ST, Kuperus JH.* Technology for FDG SPECT with a relatively inexpensive gamma camera. *Radiology 1994; 191; 461-465.*
3. *Sandler MP, Videlefsky S, Delbeke D, Patton JA, Meyerowitz C, Martin WH, Ohana I.* Evaluation of myocardial ischemia using a rest metabolism/stress perfusion protocol with fluorine - 18 deoxyglucose/Tc-99m MIBI and dual-isotope simultaneous acquisition single photon emission computed tomography. *J AM Coll Cardiol 1995; 26:870-8.*
4. *Burt RW, Perkins OW, Oppenheim BE, Schauwecker DS, Stein L, Wellman HN, Witt RM* Direct Comparison of Fluorine-18-FDG SPECT, Fluorine-18-FDG PET and Rest Thallium-201 SPECT for Detection of Myocardial Viability *J Nucl Med 1995; 36:176-179*
5. *Chen EQ, MacIntyre WJ, Go RT, Brunken RC, Saha GE, Wong CO, Neumann DR, Cook SA, Khandekar SP* Myocardial Viability Studies Using Flourine-18-FDG SPECT: A Comparison with Fluorine-18-FDG PET *J Nucl Med 1997; 38:582-586*
6. *Burt R, Witt R* Dual Isotope Imaging of F-18 FDG and Tc-99M RBC Imaging for Better Lung Tumor Localization *EJNM 1998; 25/8:PS-174*


### 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.*

# DISA SPECT

## FDG/RBC's

**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

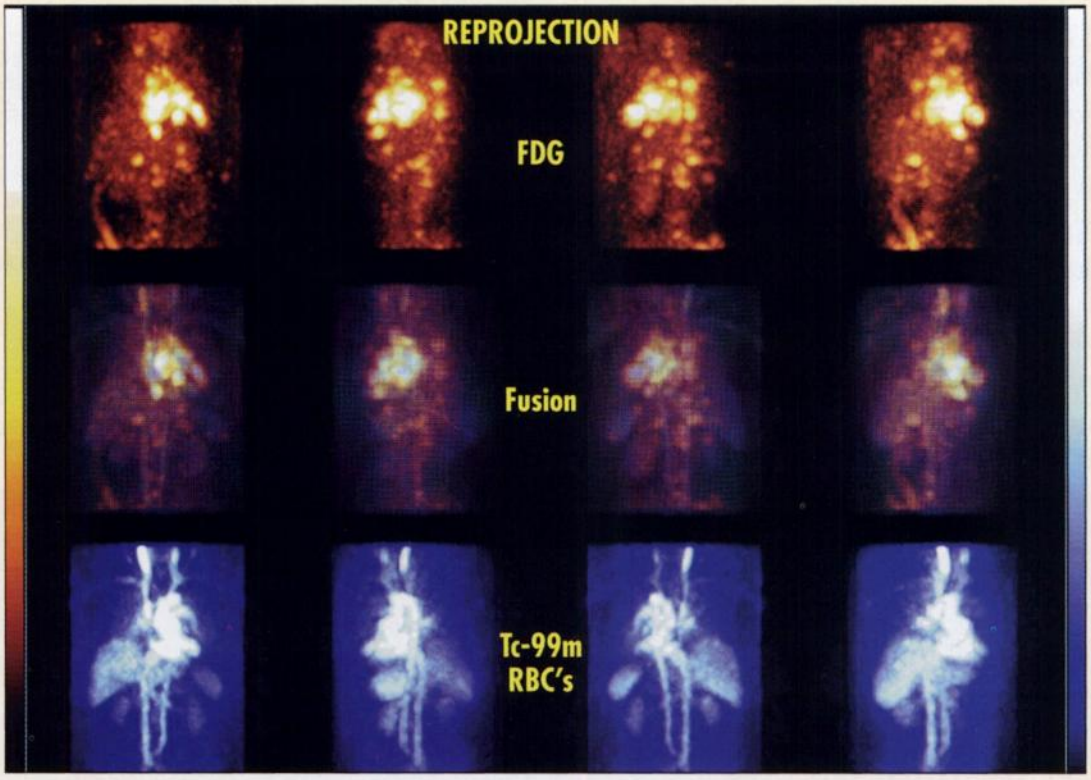
**Isotope :**
15 mCi FDG /
15 Tc-99m RBC's

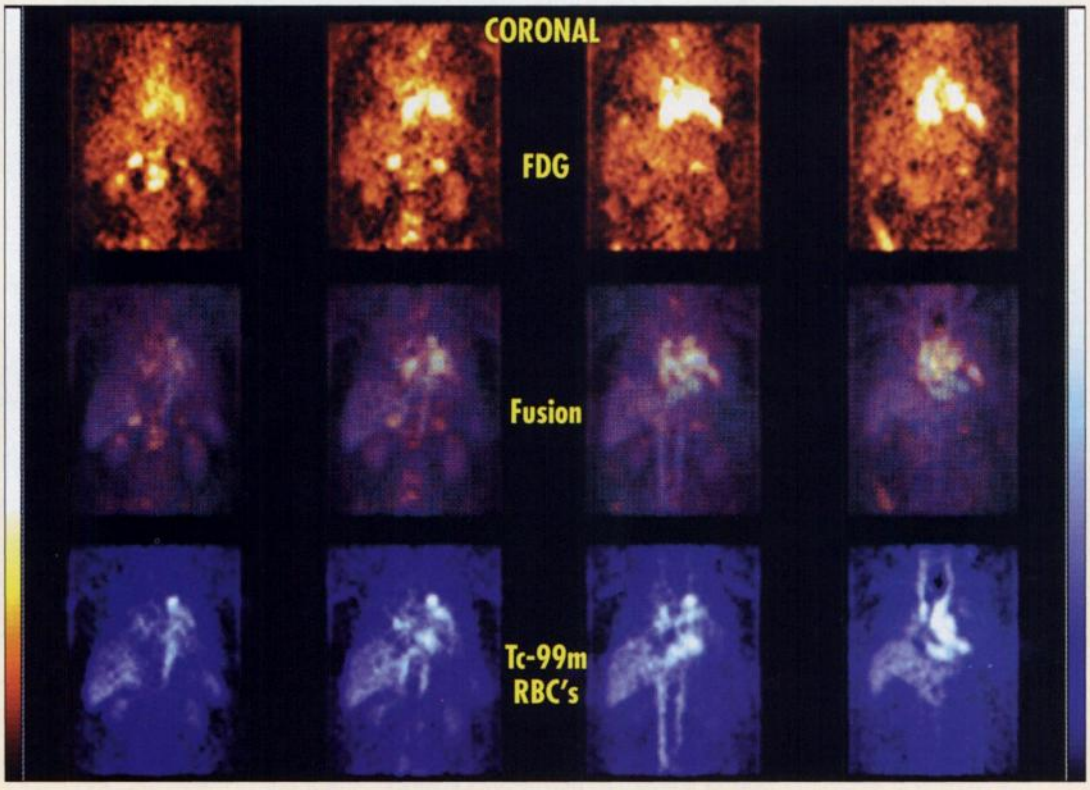
**Injection to Imaging :** 2 hrs

**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*

# QuaSAR SPECT

## *Basic Power*

## MISSION

Achieve "Quantitatively Accurate SPECT" by:

- Scatter Elimination
- Resolution Recovery
- Attenuation Correction with TCT data

## 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.

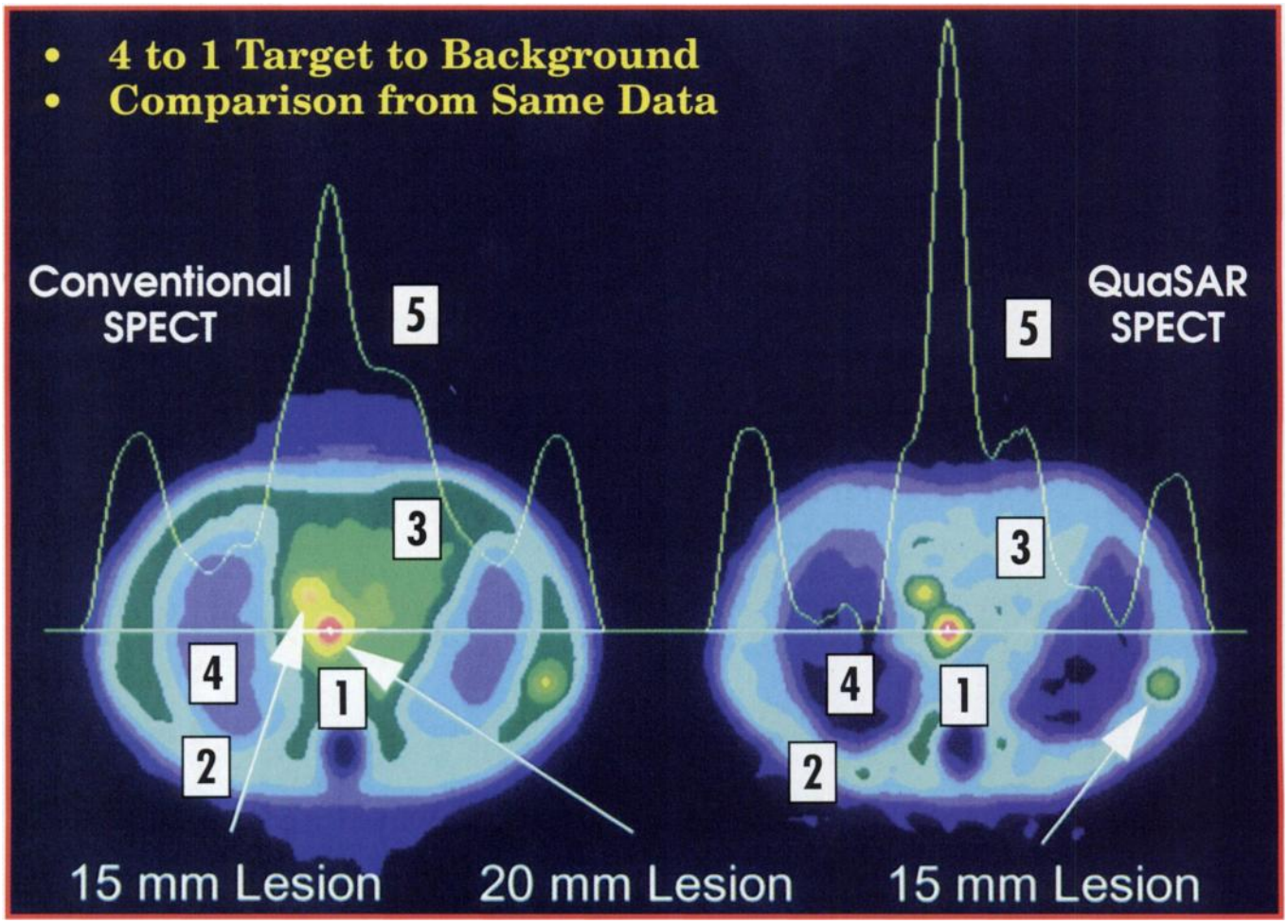
**ACTION** Attenuation Correction by Transmission Information Observation Network corrects SPECT for attenuation distortion using a measured attenuation map.

**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.

RSNA Booth #6153.




## 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.

T006018 - Rev. A 9/98

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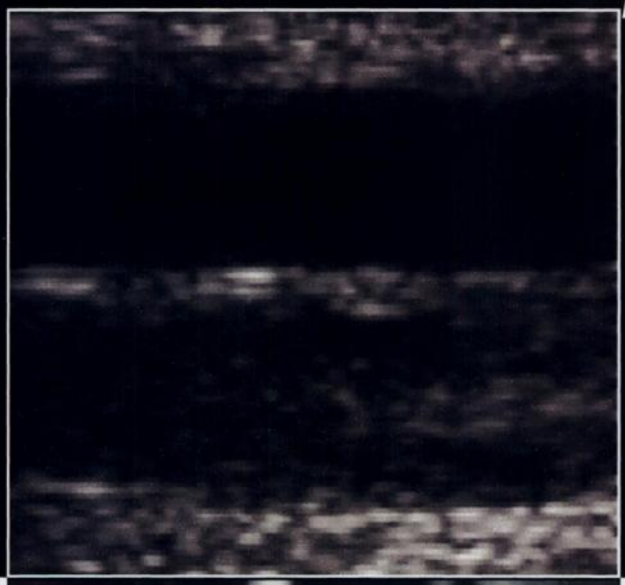
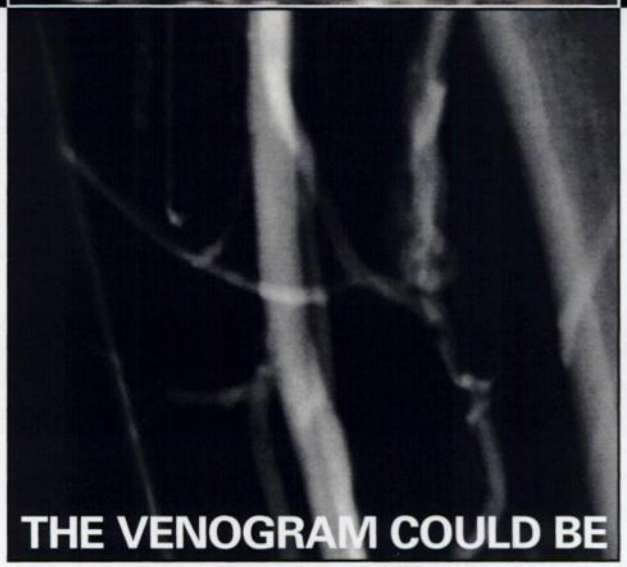
# ACUTE CLOT?

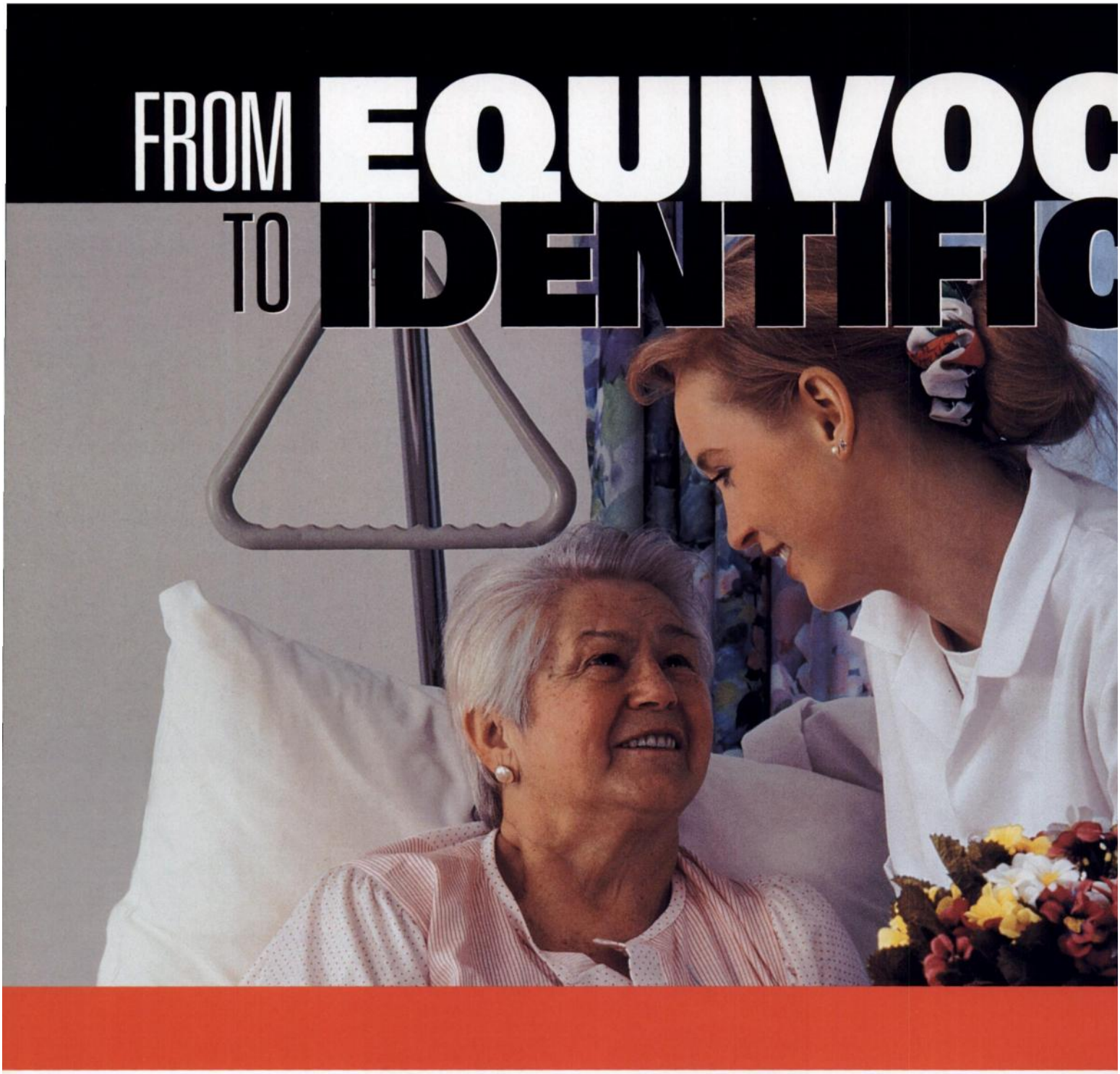
THE ULTRASOUND COULD BE
**NEGATIVE,**





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.

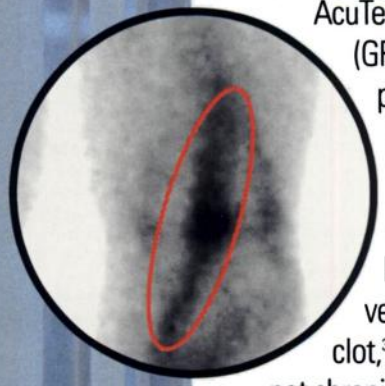
**References: 1.** AcuTect™ Prescribing Information. **2.** Becker RC. Antiplatelet therapy. *Science & Medicine.* July/August 1996:12-21. **3.** Hirsh J, Hull R. Comparative value of tests for the diagnosis of venous thrombosis. *World J Surg.* 1978;2:27-38. **4.** Bauer G. A venographic study of thrombo-embolic problems. *Acta Chir Scand.* Stockholm 1940;84(suppl 61):17.

ATION
ATION

## The first imaging modality to target acute DVT

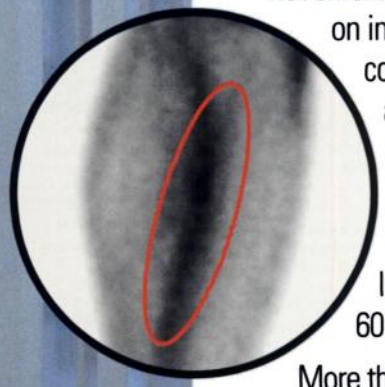
AcuTect™—a unique, radiolabeled synthetic peptide[1]—is the first to offer you the ability to clearly, safely, and comfortably target *acute* clots. AcuTect is indicated for scintigraphic imaging of acute venous thrombosis in the lower extremities of patients who have signs and symptoms of acute venous thrombosis.[1]

AcuTect binds preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets.[1,2] The result is a sensitivity that challenges the "gold standard."



Increased tracer uptake at knee/popliteal vein

In clinical studies, blindly read AcuTect demonstrated 56-73% agreement with blindly read venography.[1] While venography detects the presence of any clot,[3,4] AcuTect appears to detect acute and not chronic venous thrombosis. (This is based on in vivo and ex vivo animal data; not confirmed clinically.[1]) Therefore, 100% agreement between AcuTect and venography is not expected.



Increased tracer uptake in left calf

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.**

NEW

# ACUTECT™

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

**The difference is acute.**

Diatide, Inc.

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Please see brief summary of prescribing information on following page.

# NEW AcuTect

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

### BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please consult Full Product Information before using.

### DESCRIPTION

AcuTect™, 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 µg of bibapcitide, 75 mg of sodium glucoheptonate dihydrate, 89 µg of stannous chloride dihydrate, 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 apcitide monomers. When sterile, nonpyrogenic Sodium Pertechnetate Tc 99m Injection in 0.9% 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:** 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.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** 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. A fully equipped emergency cart, or equivalent supplies and equipment, and personnel competent in recognizing and treating anaphylactic reactions should be available. (See Adverse Reactions Section.)

### PRECAUTIONS

***General***

The contents of AcuTect™ Kit are intended only for use in the preparation of technetium Tc 99m apcitide, and are not to be administered to the patient without reconstitution.

Hypersensitivity: Small peptides may be immunogenic. Of 642 patients observed for 3 hours after AcuTect™ injection and of whom 169 were monitored for 24 hours, one patient had acute hypotension that began within 10 minutes of injection and, over 60 minutes, progressed to a systolic pressure of 70 mm Hg.

In preliminary studies of IgG binding to apcitide by ELISA assay, IgG binding was not detected. Other measures of immune function (e.g., complement, immune complexes, lymphokines) have not been studied. In preclinical animal models, there was a reduction in the absolute or relative weight of the spleen. The clinical significance of the reduced splenic weight to immune function is not known.

Technetium Tc 99m apcitide, like other radioactive drugs, must be handled with care and appropriate safety measures should be taken to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with appropriate patient management.

Radiopharmaceutical agents 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 governmental agency authorized to license the use of radionuclides.

Urinary excretion of radioactivity occurs over about 24 hours (with 75% occurring during the first 8 hours). Special precautions, such as bladder catheterization, should be taken with incontinent patients to minimize the risk of radioactive contamination of clothing, bed linen, and the patient's environment. Studies have not been done to evaluate the need to adjust the dose of AcuTect™ in patients with renal impairment.

***Information for Patients***

To minimize the absorbed radiation dose to the bladder, adequate hydration should be encouraged to ensure frequent voiding during the first few hours after AcuTect™ injection. To help protect themselves and others in their environment, patients need to take the following precautions for 12 hours following injection. Whenever possible, a toilet should be used, rather than a urinal, and the toilet should be flushed several times after each use. Spilled urine should be cleaned up completely. Patients should wash their hands thoroughly after each voiding. If blood or urine gets onto clothing, the clothing should be washed separately.

***Laboratory Tests***

AcuTect™ has been shown to inhibit platelet aggregation. The effect of AcuTect™ on bleeding time in humans has not been studied.

Moderate elevations in liver enzymes were noted in rare cases at three hours and persisted to at least 24 hours following administration of AcuTect™.

***Drug Interactions***

Clinically detectable drug interactions were not seen or explicitly studied in patients who received technetium Tc 99m apcitide and other concomitant medications. The effect of drugs that increase or decrease prothrombin time on the binding of AcuTect™ to activated platelets has not been studied.

The effect of heparin, warfarin, or aspirin on apcitide binding has not been studied in humans. In animal in vitro and ex vivo models, heparin or aspirin did not change the inhibition of platelet aggregation caused by apcitide. Whether heparin or aspirin change the ability of apcitide to bind to GPIIb/IIIa receptors on activated platelets was not studied. The effect of the duration of anticoagulation on apcitide binding was not studied.

***Carcinogenesis, Mutagenesis, Impairment of Fertility***

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. AcuTect™ was not mutagenic in the Ames test or mouse lymphoma test, and it was not clastogenic in the mouse micronucleus test.

***Pregnancy***

Pregnancy Category C. Animal reproduction studies have not been conducted with technetium Tc 99m apcitide. It is not known whether technetium Tc 99m apcitide or the other peptide components of the formulation can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m apcitide should be given to a pregnant woman only if clearly needed. Studies in pregnant women have not been conducted.

***Nursing Mothers***

Technetium Tc 99m pertechnetate is excreted in human milk. It is not known whether technetium Tc 99m apcitide is excreted in human milk. Caution should be exercised when technetium Tc 99m apcitide is administered to nursing women. Wherever possible, infant formula should be substituted for breast milk until the technetium has been eliminated.

***Pediatric Use***

Safety and effectiveness in pediatric patients have not been established.

### 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 µg of bibapcitide. Of these adults, 46% were women and 54% men. The mean age was 57.0 years (17 to 95 years). In all patients, adverse events were monitored for at least 3 hours. In a subset of 169 patients, adverse events were monitored for 24 hours. Deaths did not occur during the clinical study period. Following injection of technetium Tc 99m apcitide, a serious episode of hypotension occurred in one patient who had acute hypotension that began within 10 minutes of injection and, over 60 minutes, progressed to a systolic pressure of 70 mm Hg.

At least one adverse event occurred in 29/642 (4.5%) of patients after technetium Tc 99m apcitide injection. Pain was the most commonly reported adverse event ( 1.7% of patients or healthy volunteers). Table 1 lists adverse events reported in 0.5% or more of patients who received technetium Tc 99m apcitide.

**Table 1: Adverse Events Reported in ≥0.5 % of Patients Following AcuTect™ Injection in Clinical Studies**

| | |
|---|---|
| Number of Patients Exposed to AcuTect™ | 642 |
| Number of Patients with at Least One Adverse Event | 29 (4.5%) |
| Body as a Whole | 21 (3.3%) |
| Pain (back, leg, chest) | 11 (1.7%) |
| Headache | 5 (0.8%) |
| Cardiovascular System | 13 (2.0%) |
| Hypotension | 5 (0.8%) |
| Hypertension | 3 (0.5%) |

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

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

**DOSAGE AND ADMINISTRATION:** To detect acute venous thrombosis in a lower extremity, reconstituted AcuTect™ should be administered as a peripheral intravenous injection in an upper extremity, at a dose of approximately 100 µg of bibapcitide radiolabeled with 20 mCi of technetium 99m.

Technetium Tc 99m apcitide should be drawn into the syringe and administered using sterile technique. If nondisposable equipment is used, scrupulous care should be taken to prevent residual contamination with traces of cleansing 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 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 reinjection. The safety of more than one dose has not been studied.

Positive AcuTect™ uptake in the deep venous structures is defined as asymmetric vascular uptake (with or without superimposed diffuse 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 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 apcitide are listed in Table 2. The values are listed in descending order as rad/mCi and mGy/MBq and assume urinary bladder emptying at 4.8 hours.

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

| Target Organ | rad/mCi | mGy/MBq |
|---|---|---|
| Urinary Bladder Wall | 0.22 | 0.060 |
| Kidneys | 0.050 | 0.014 |
| Upper Large Intestine Wall | 0.039 | 0.010 |
| Lower Large Intestine Wall | 0.037 | 0.010 |
| Uterus | 0.034 | 0.0092 |
| Thyroid Gland | 0.022 | 0.0060 |
| Testes/Ovaries | 0.020/0.023 | 0.0053/0.0063 |
| Lungs | 0.016 | 0.0043 |
| Red Marrow | 0.0091 | 0.0025 |
| Breasts | 0.0050 | 0.0013 |

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 18, 1-4, 1988) and gave a value of 0.0093mSv/MBq (0.0034 rem/mCi).

### HOW SUPPLIED

Each kit contains one vial containing a sterile, nonpyrogenic, freeze-dried mixture of bibapcitide, 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). Store the reconstituted 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.
9 Delta Drive, Londonderry, New Hampshire 03053

Rev. September 1998
Distributed by: Diatide, Inc. and Nycomed Amersham
60-801980



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**BRIEF SUMMARY**

# ADENOSCAN®
## adenosine

**For Intravenous Infusion Only**

**DESCRIPTION**

Adenosine is an endogenous nucleoside occurring in all cells of the body. It is chemically 6-amino-9-beta-D-ribofuranosyl-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, q.s. The pH of the solution is between 4.5 and 7.5.

**INDICATIONS AND USAGE:**

Intravenous Adenoscan is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy 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 bronchoconstrictive or bronchospastic lung disease (e.g., asthma).
4. Known hypersensitivity to adenosine.

**WARNINGS:**

***Fatal Cardiac Arrest, Life Threatening Ventricular Arrhythmias, and Myocardial Infarction.***

Fatal cardiac arrest, sustained ventricular tachycardia (requiring resuscitation), and nonfatal myocardial infarction have been reported coincident with Adenoscan infusion. Patients with unstable angina may be at greater risk.

***Sinoatrial and Atrioventricular Nodal Block***

Adenoscan (adenosine) exerts a direct 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 6.3% of patients develop AV block with Adenoscan, including first-degree (2.9%), second-degree (2.6%) and third-degree (0.8%) heart block. All episodes of AV block have been asymptomatic, transient, and did not require intervention. Adenoscan can cause 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 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 infusions.

***Hypotension***

Adenoscan (adenosine) is a potent peripheral vasodilator and can cause significant hypotension. Patients with an intact baroreceptor reflux 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, pericarditis or pericardial effusions, stenotic carotid artery disease with cerebrovascular insufficiency, or uncorrected hypovolemia, due to the risk of hypotensive complications in these patients. Adenoscan should be discontinued in any patient who develops persistent or symptomatic hypotension.

***Hypertension***

Increases in systolic and diastolic pressure have been observed (as great as 140 mm Hg systolic in one case) concomitant 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 activation of carotid body chemoreceptors) and intravenous administration in man has been shown to increase minute ventilation (Ve) and reduce arterial $PCO_2$ 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. Adenosine administered by inhalation has been reported to cause bronchoconstriction in asthmatic patients, presumably due to mast cell degranulation and histamine release. These effects have not been observed in normal subjects. Adenoscan has been administered to a limited number of patients with asthma and mild to moderate exacerbation of their symptoms has been reported. Respiratory compromise has occurred during adenosine infusion in patients with obstructive pulmonary disease. Adenoscan should be used with caution in patients with obstructive lung disease not associated with bronchoconstriction (e.g., emphysema, bronchitis, etc.) and should be avoided in patients with bronchoconstriction or bronchospasm (e.g., asthma). Adenoscan should be discontinued in any patient who develops severe respiratory difficulties.

**PRECAUTIONS:**

***Drug Interactions***

Intravenous Adenoscan (adenosine) has been given with other cardioactive drugs (such as beta adrenergic blocking agents, cardiac 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 vasoactive effects of Adenoscan are inhibited by adenosine receptor antagonists, such as alkylxanthines (e.g., caffeine and theophylline). The safety and efficacy of Adenoscan in the presence of these agents has not been systematically evaluated. The vasoactive effects of Adenoscan are potentiated by nucleoside transport inhibitors, such as dipyridamole. The safety and efficacy of Adenoscan in the presence of dipyridamole has not been systematically evaluated. Whenever possible, drugs that might inhibit or augment the effects of adenosine should be withheld for at least five half-lives prior to the use of Adenoscan.

***Carcinogenesis, 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 Microsome Assay.

Adenosine, however, like other nucleosides at millimolar concentrations present for several doubling times of cells in culture, is known to produce a variety of chromosomal alterations. In rats and mice, adenosine administered intraperitoneally once a day for five days at 50, 100, and 150 mg/kg [10-30 (rats) and 5-15 (mice) times human dosage on a mg/$M^2$ basis] caused decreased spermatogenesis and increased numbers of abnormal sperm, a reflection of the ability of adenosine to produce chromosomal damage.

***Pregnancy Category C***

Animal reproduction studies have not been conducted with adenosine; nor have 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 1421 patients enrolled in controlled and uncontrolled U.S. clinical trials. Despite the short half-life of adenosine, 10.6% of the side effects occurred not with the infusion of Adenoscan but several hours after the infusion terminated. Also, 8.4% of the side effects that began coincident with the infusion persisted for up to 24 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 | 40% | Lightheadedness/dizziness | 12% | Paresthesia | 2% |
| Dyspnea or urge to breathe deeply | 28% | Upper extremity discomfort | 4% | Hypotension | 2% |
| Headache | 18% | ST segment depression | 3% | Nervousness | 2% |
| Throat, neck or jaw discomfort | 15% | First-degree AV block | 3% | Arrhythmias | 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 arrhythmia; third-degree AV block; bradycardia; palpitation; sinus exit block; sinus pause; sweating; T-wave changes, hypertension (systolic blood pressure > 200 mm Hg).

**Central Nervous System:** drowsiness; emotional instability; tremors.

**Genital/Urinary System:** vaginal pressure; urgency.

**Respiratory System:** cough.

**Special Senses:** blurred vision; dry mouth; ear discomfort; metallic taste; nasal congestion; scotomas; tongue discomfort.

**OVERDOSAGE:**

The half-life of Adenosine is less than 10 seconds and side effects of Adenoscan (when they occur) usually resolve quickly when the infusion is discontinued, although delayed or persistent effects have been observed. Methylxanthines, such as caffeine and theophylline, 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 slow 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 six minutes (total dose of 0.84 mg/kg).

The required dose of thallium-201 should be injected at the midpoint of the Adenoscan infusion (i.e., after the first three minutes of Adenoscan). Thallium-201 is physically compatible with Adenoscan and may be injected directly into the Adenoscan infusion set.

The injection should be as close to the venous access as possible to prevent an inadvertent increase in the dose of Adenoscan (the contents of the IV tubing) being administered. There are no data on the safety or efficacy of alternative Adenoscan infusion protocols.

The safety and efficacy of Adenoscan administered by the intracoronary 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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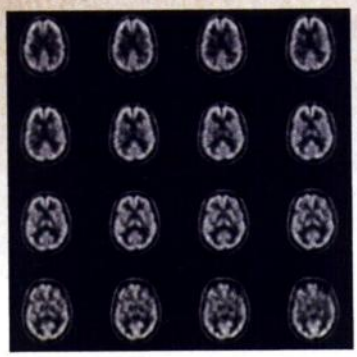

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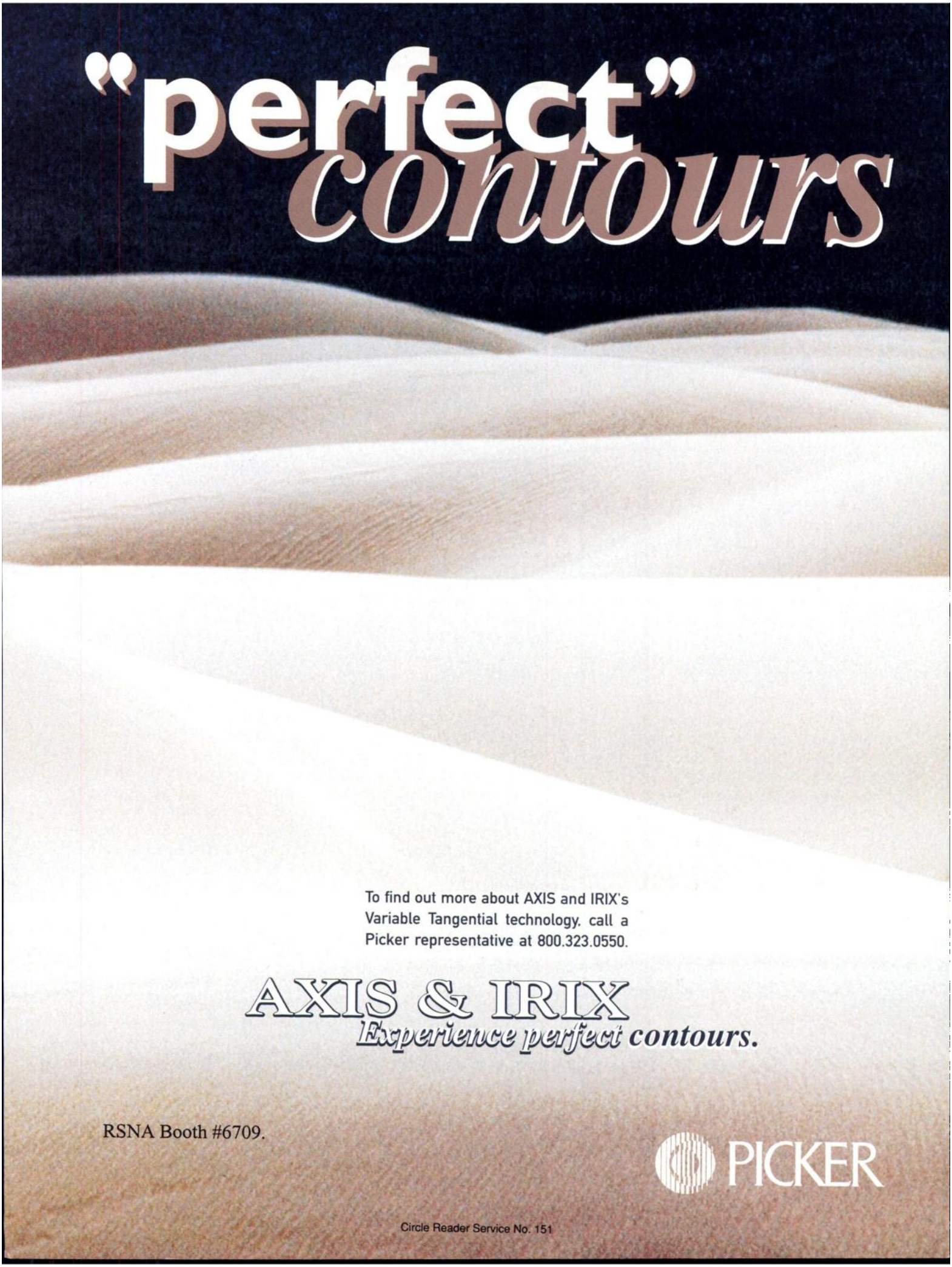
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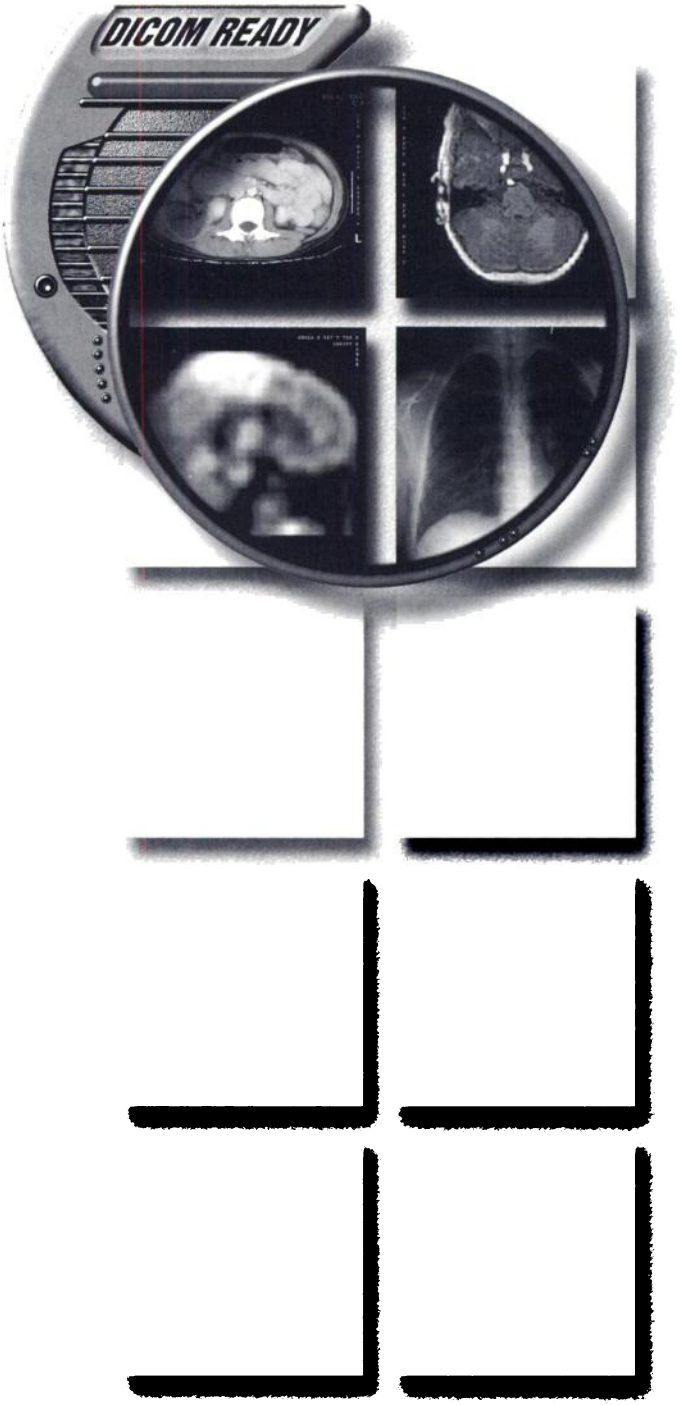


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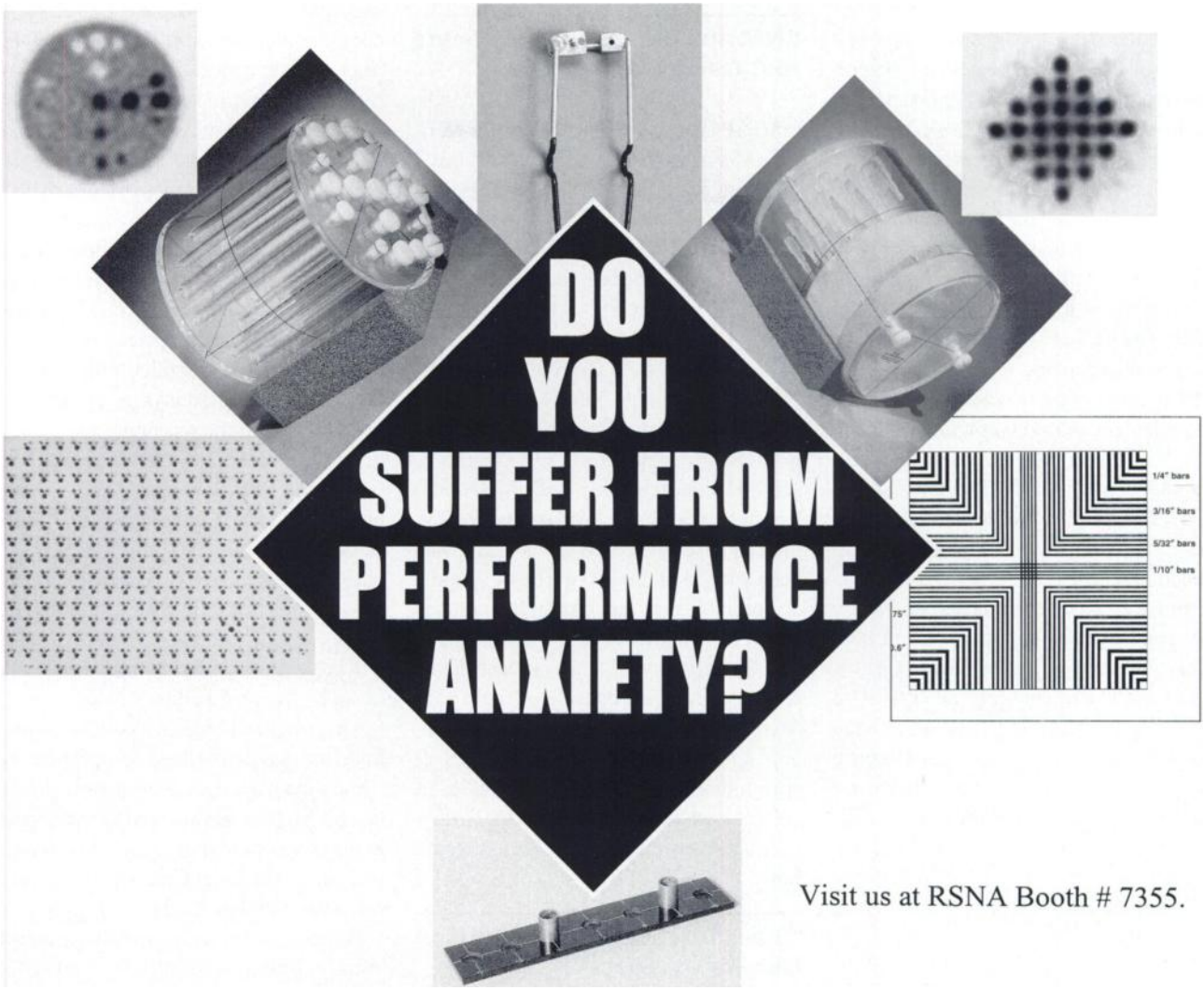


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- Rapid GI clearance

# A convenient view.

- Room temperature preparation, and 8 hour reconstituted shelf-life
- No redistribution
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# 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.

**Brief Summary**

# MYOVIEW™

## Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection

**Diagnostic radiopharmaceutical For intravenous use only**
**Code N166A**

### DESCRIPTION

The Medi-Physics Myoview™ kit is supplied as a pack of five vials for use in the preparation of a technetium Tc99m tetrofosmin intravenous injection to be used for the scintigraphic delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium. Each vial contains a pre-dispensed, sterile, non-pyrogenic, lyophilized mixture of 0.23 mg tetrofosmin [6,9-bis(2-ethoxyethyl)-3,12-dioxa-6,9-diphospha-tetradecane], 30 µg stannous chloride dihydrate (minimum stannous tin 5.0 µg; maximum total stannous and stannic tin 15.8 µg), 0.32 mg disodium sulphosalicylate and 1.0 mg sodium D-gluconate, and 1.8 mg sodium hydrogen carbonate. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

**Caution: Federal (USA) law prohibits dispensing without a prescription**

### CLINICAL PHARMACOLOGY

**General**
When technetium Tc99m pertechnetate is added to tetrofosmin in the presence of stannous reductant, a lipophilic, cationic technetium Tc99m complex is formed, Tc99m tetrofosmin. This complex is the active ingredient in the reconstituted drug product, on whose biodistribution and pharmacokinetic properties the indications for use depend.

**Clinical Trials**
A total of 252 patients with ischemic heart disease or atypical chest pain who had a reason for exercise stress imaging were studied in two open-label, multi center, clinical trials of Tc99m tetrofosmin (study a and study b). Of these 252 patients there were 212 (83%) males and 40 (17%) females with a mean age of 60.5 years (range 33.7 to 82.4 years). At peak exercise, maximum heart rate achieved and peak systolic blood pressure were comparable after Myoview and thallium-201 exercise studies.

All patients had exercise and rest planar imaging with Myoview and thallium-201; 191 (76%) patients also had SPECT imaging. The Myoview and thallium-201 images were separated by a mean of 5.1 days (1-14 days before or 2-14 days after Myoview). For Myoview imaging, each patient received 185-296 MBq (5-8 mCi) Tc99m tetrofosmin at peak exercise and 555-888 MBq (15-24 mCi) Tc99m tetrofosmin at rest approximately 4 hours later. For thallium-201 imaging, patients received thallium-201 55.5-74 MBq (1.5-2.0 mCi) at peak exercise.

The images were evaluated for the quality of the image (excellent, good or poor) and the diagnosis (with scores of 0 = normal, 1 = ischemia, 2 = infarct, 3 = mixed infarct and ischemia). The primary outcome variable was the percentage of correct diagnoses in comparison to the final clinical diagnosis. All planar images were blindly read; SPECT images were evaluated by the unblinded investigator. A subset of 181/252 (71%) patients had coronary angiography comparisons to the planar images of Myoview or thallium-201.

### INDICATIONS AND USAGE

Myoview is indicated for scintigraphic imaging of the myocardium following separate administrations under exercise and resting conditions. It is useful in the delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium.

### CONTRAINDICATIONS

None known.

### WARNINGS

In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.

### PRECAUTIONS

**General**
To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often thereafter as possible. Adequate hydration should be encouraged to permit frequent voiding.

The contents of the Myoview vial are intended only for use in the preparation of technetium

Tc99m tetrofosmin injection and are NOT to be administered directly to the patient.

As with all injectable drug products, allergic reactions and anaphylaxis may occur.

Sometimes Tc99m labeled myocardial imaging agents may produce planar and SPECT images with different imaging information.

Technetium Tc99m tetrofosmin injection, like other radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

Drug Interactions: Drug interactions were not noted and were not studied in clinical studies in which Myoview was administered to patients receiving concomitant medication. Drugs such as beta blockers, calcium blockers and nitrates may influence myocardial function and blood flow. The effects of such drugs on imaging results are not known.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**
Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. Tetrofosmin sulphosalicylate was not mutagenic *in vitro* in the Ames test, mouse lymphoma, or human lymphocyte tests, nor was it clastogenic *in vivo* in the mouse micronucleus test.

**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. Therefore, 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. Six 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 5/764 (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 renally 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 µGy/MBq and assume urinary bladder emptying at 3.5 hours.

**Table 1**
Estimated Absorted Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

| | Absorbed radiation dose | | | |
|---|---|---|---|---|
| | Exercise | | Rest | |
| Target Organ | rad/mCi | µGy/MBq | rad/mCi | µGy/MBq |
| Gall bladder wall | 0.123 | 33.2 | 0.180 | 48.6 |
| Upper large intestine | 0.075 | 20.1 | 0.113 | 30.4 |
| Bladder wall | 0.058 | 15.6 | 0.071 | 19.3 |
| Lower large intestine | 0.057 | 15.3 | 0.082 | 22.2 |
| Small intestine | 0.045 | 12.1 | 0.063 | 17.0 |
| Kidney | 0.039 | 10.4 | 0.046 | 12.5 |
| Salivary glands | 0.030 | 8.04 | 0.043 | 11.6 |
| Ovaries | 0.029 | 7.88 | 0.035 | 9.55 |
| Uterus | 0.027 | 7.34 | 0.031 | 8.36 |
| Bone surface | 0.023 | 6.23 | 0.021 | 5.58 |
| Pancreas | 0.019 | 5.00 | 0.018 | 4.98 |
| Stomach | 0.017 | 4.60 | 0.017 | 4.63 |
| Thyroid | 0.016 | 4.34 | 0.022 | 5.83 |
| Adrenals | 0.016 | 4.32 | 0.015 | 4.11 |
| Heart wall | 0.015 | 4.14 | 0.015 | 3.93 |
| Red marrow | 0.015 | 4.14 | 0.015 | 3.97 |
| Spleen | 0.015 | 4.12 | 0.014 | 3.82 |
| Muscle | 0.013 | 3.52 | 0.012 | 3.32 |
| Testes | 0.013 | 3.41 | 0.011 | 3.05 |
| Liver | 0.012 | 3.22 | 0.015 | 4.15 |
| Thymus | 0.012 | 3.11 | 0.009 | 2.54 |
| Brain | 0.010 | 2.72 | 0.008 | 2.15 |
| Lungs | 0.008 | 2.27 | 0.008 | 2.08 |
| Skin | 0.008 | 2.22 | 0.007 | 1.91 |
| Breasts | 0.008 | 2.22 | 0.007 | 1.83 |

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), 1988) and gave values of 8.61 x $10^{-3}$ mSv/MBq and 1.12 x $10^{-2}$ mSv/MBq after exercise and rest respectively.

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

Distributed by: Medi-Physics, Inc., Amersham Healthcare
2636 S. Clearbrook Dr., Arlington Heights, IL 60005
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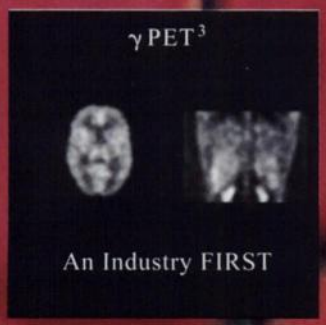


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SOCIETY OF NUCLEAR MEDICINE

# 46th Annual Meeting

LOS ANGELES, CALIFORNIA

## June 6 -10, 1999


### INQUIRIES:

**Society of Nuclear Medicine**
Department: Meeting Services
1850 Samuel Morse Drive
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 |
| Last Day for Housing Reservations: | April 29, 1999 |
| Abstract Submission Deadline: | January 8, 1999 |

### REGISTRATION FEES:

#### Categorical

| **Saturday**, June 5, 1999 | **Pre-Registration** | **On-Site** |
|---|---|---|
| Member | $115 | $135 |
| Non-Member | $145 | $165 |

*(Boxed lunch is provided for the Saturday Categorical only, the cost of which is included in the fee)*

#### Categoricals

| **Sunday**, June 6, 1999 | **Pre-Registration** | **On-Site** |
|---|---|---|
| Member | $100 | $120 |
| Non-Member | $130 | $150 |

#### Continuing Education

**Monday**, June 7, 1999 through **Thursday**, June 10, 1999

| **Member** | **Pre-Registration** | **On-Site** |
|---|---|---|
| Physician/Scientist/Pharmacist | $335 | $395 |
| Technologist | $205 | $255 |
| **Non-Member** | | |
| Physician/Scientist/Pharmacist | $530 | $590 |
| Technologist | $395 | $450 |
| Companion | $55 | $55 |

### EXHIBITS:

Monday, June 7, 1999 through Thursday, June 10, 1999
Exhibit space is $21.50 per square foot.
Contact Jane Day at jday@snm.org for further information.

### HOW TO OBTAIN PRE-REGISTRATION AND HOUSING FORMS:

1. The SNM Web Site, www.snm.org, starting January
2. Fax-On-Demand*, starting January
3. The Journal of Nuclear Medicine, February Issue
4. The Journal of Nuclear Medicine Technology, March Issue

### HOW TO OBTAIN A FREE COPY OF THE SOFTWARE THAT YOU WILL NEED TO SUBMIT YOUR ABSTRACT:

1. DOWNLOAD Submitter Assistant Software for the PC/Mac from the SNM Web Site at www.snm.org -or-
2. REQUEST a copy of the Submitter Assistant on diskette from Medical Support Systems (MSS) at:

Attn: Submitter Assistant Request
Society of Nuclear Medicine
1000 Massachusetts Avenue, 3rd Floor
Cambridge, MA 02138-5394
USA

Phone: (800) 375-2586 (USA), (617) 492-0509 (International)
FAX: (800) 830-2586 (USA), (617) 876-5351 (International)
E-mail: snmabs@dbpub.com

**Please specify PC or Macintosh.**

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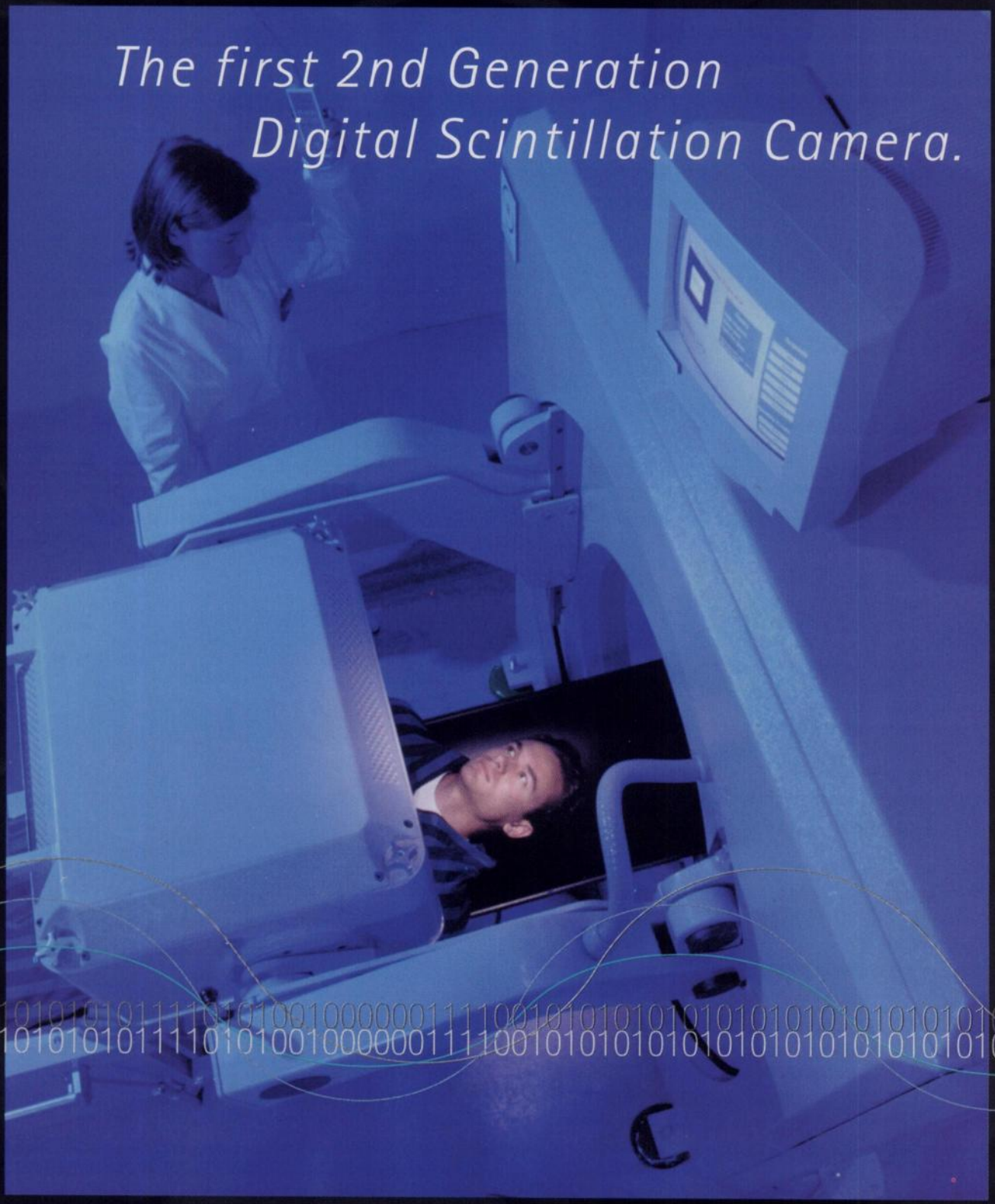

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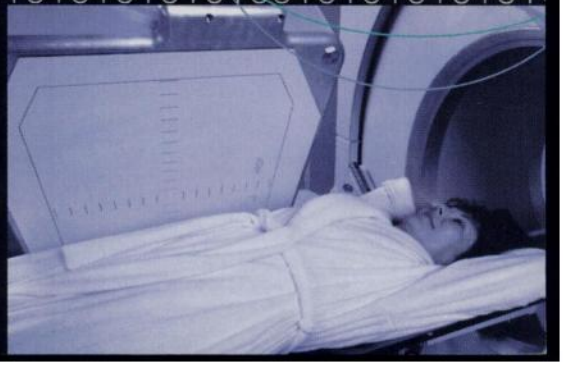

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# Call for Abstracts

**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*.

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**.

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

# Paul C. Aebersold Award

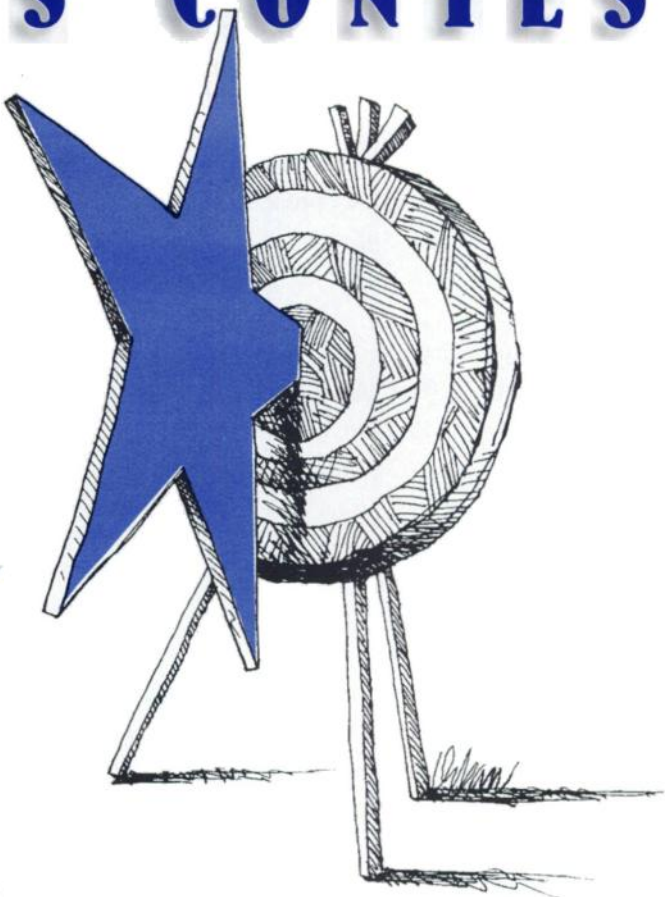
Applications are invited for the 1999 Paul C. Aebersold Award for outstanding achievement in basic science applied to Nuclear Medicine. This award commemorates the contributions of Dr. Paul Clarence Aebersold to the applications of nuclear physics to Nuclear Medicine and radiation biology, as well as 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.

# PR-STARS CONTEST

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 $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.

**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:** $350 for the individual and $250 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 from) 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*

# PR - STARS CONTEST

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

**Eligibility:**
- ★ Nuclear Medicine Technologist
- ★ Staff member of a hospital or nuclear medicine facility
- ★ Entry postmarked by December 1, 1998
- ★ All of the following questions answered in full

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 |

9. 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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*The Handbook is not a substitute for any regulation or license condition and is not endorsed by the NRC.

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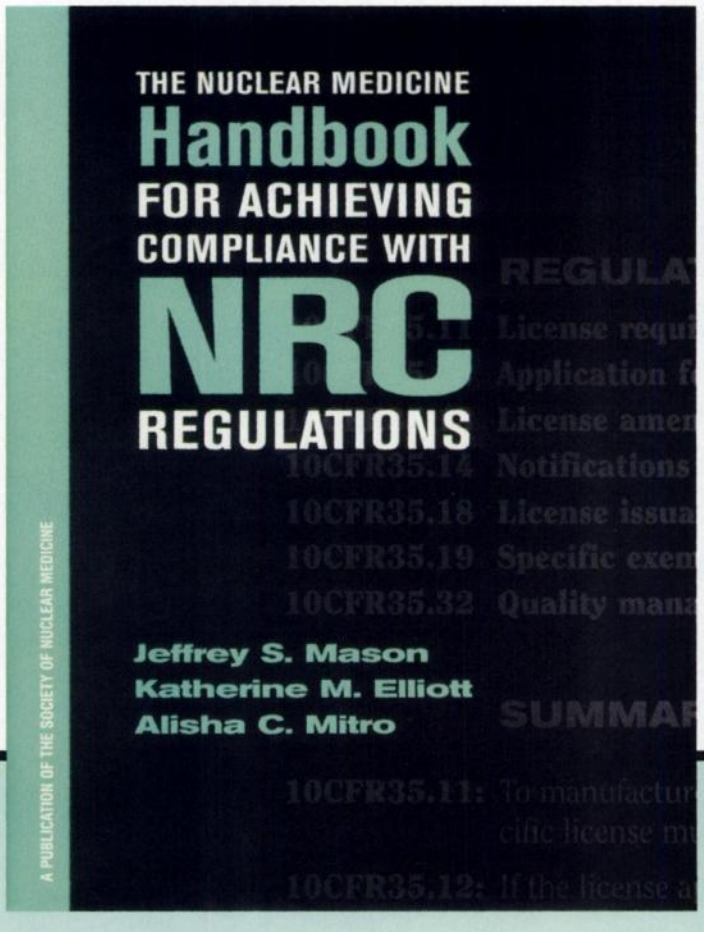
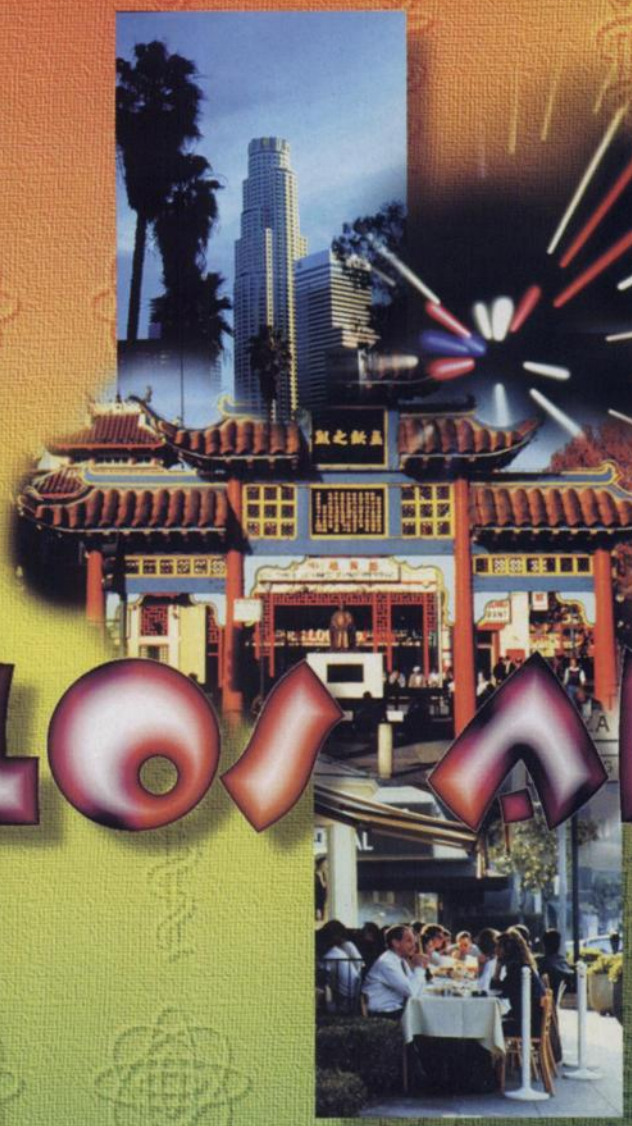


SOCIETY OF NUCLEAR MEDICINE



# See you in LOS ANGELES

*46th Annual Meeting*
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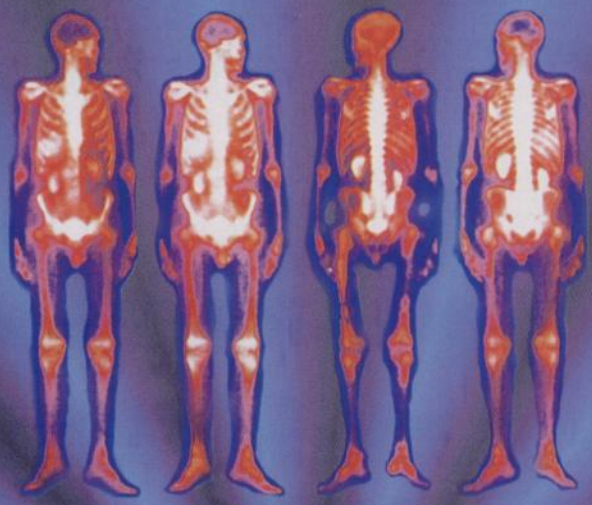

SNM PEP

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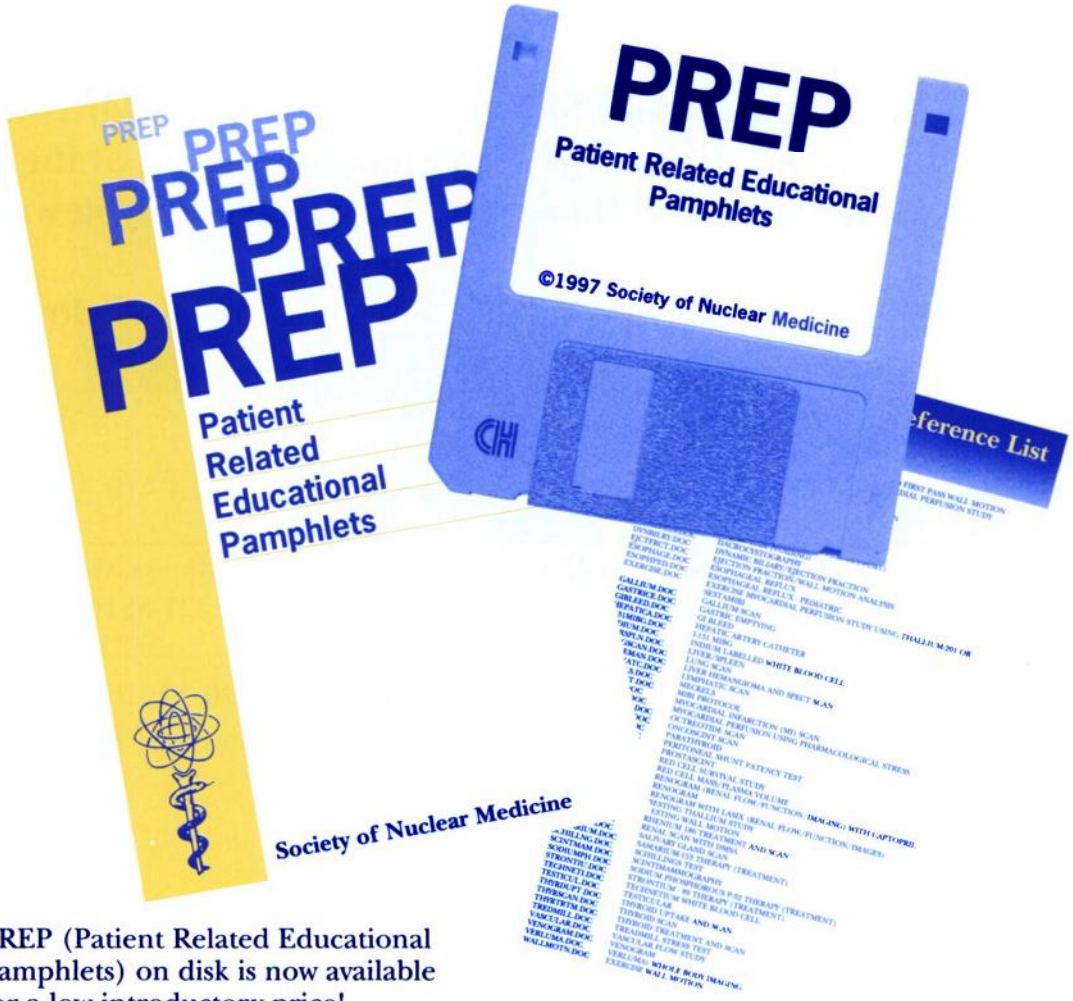


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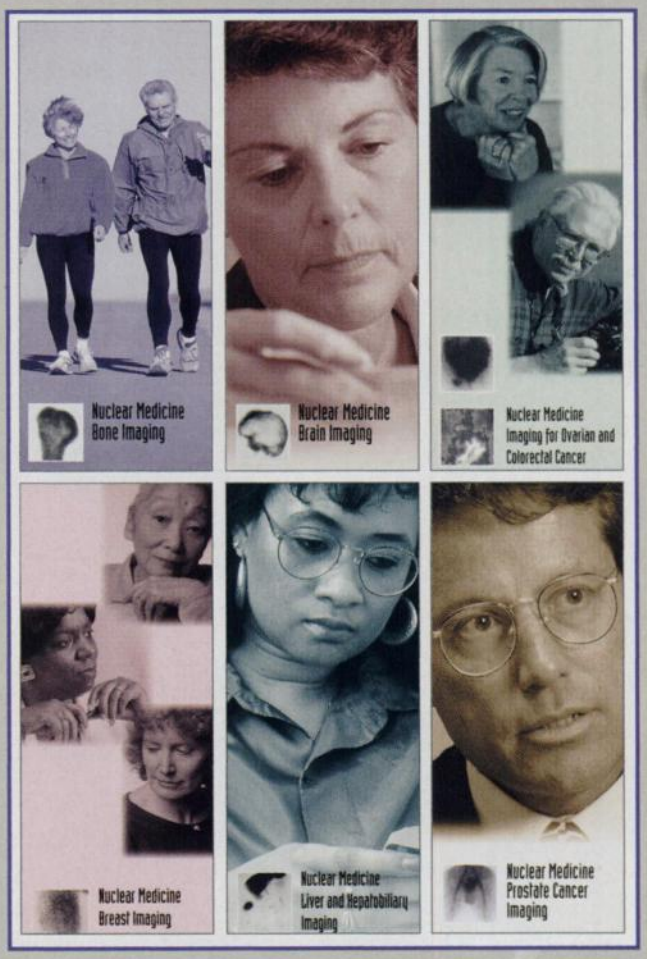


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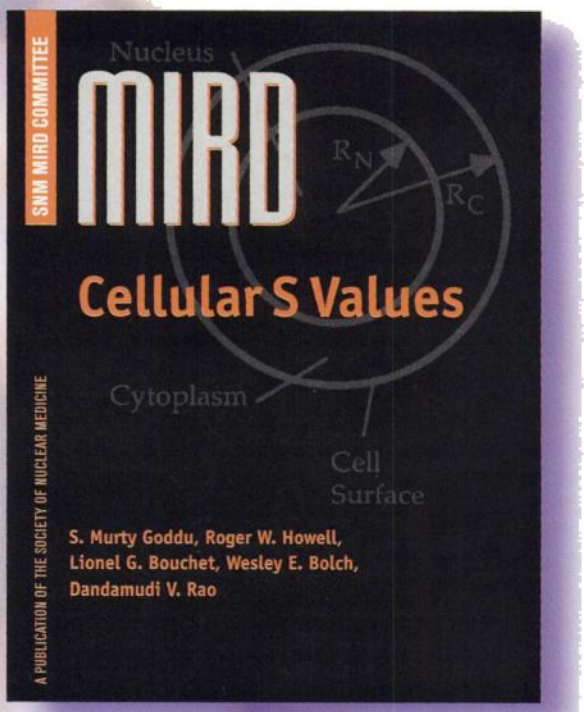
# NEW AND NOTABLE FROM THE SOCIETY OF NUCLEAR MEDICINE MIRD COMMITTEE...

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.

## MIRD CELLULAR S VALUES




Cellular absorbed-dose estimates play an important role in evaluating the relative merits of different radionuclides and radiopharmaceuticals in improving the overall safety and efficacy of diagnostic and therapeutic nuclear medicine.

*MIRD Cellular S Values* provides nuclear medicine facilities the data necessary in estimating absorbed dose at the cellular level from intracellularly localized radionuclides using cellular S values for emitters of monoenergetic electrons and alpha particles.

A thorough introduction explains the Cellular Model and Cellular Dosimetry, along with examples in the use of the tables. Three appendices include cellular S values for Selected Radionuclides, Monoenergetic Electron Emitters, and Monoenergetic Alpha Particle Emitters.

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## MIRD PRIMER FOR ABSORBED DOSE CALCULATIONS

**Revised Edition**

The *MIRD Primer* is unquestionably the standard reference on absorbed dosage of radiopharmaceuticals in human beings, offering a thorough review of absorbed dose calculations used in the application of radiopharmaceuticals to medical studies. Included are detailed explanations of MIRD schema, examples of the application of the schema, dose estimates and technical appendices.

## MIRD RADIONUCLIDE DATA AND DECAY SCHEMES

A thorough compilation of decay schemes and output tables for 242 radionuclides. Detailed information on radiation energy and intensity and on emissions in the decay of radionuclides. Supplies the basis for key commonly used computations, such as calculation of absorbed dose, assay of radioactivity, and evaluation of radionuclide purity.

**Visit the SNM Web site: http://www.snm.org**

RADIOLOGY SUPPORT DEVICES INC.

## CRITICAL QUESTIONS

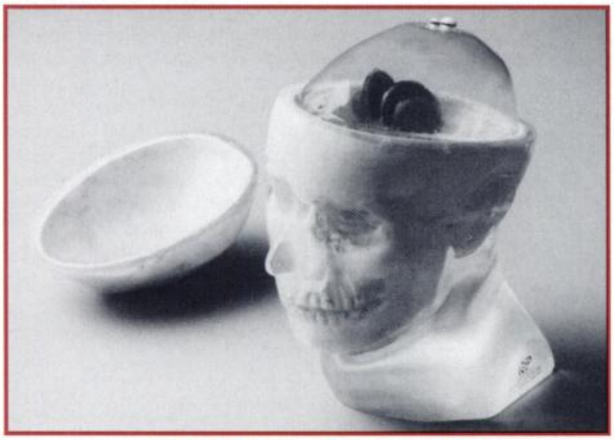
When no lesion can be detected in a nuclear scan of the breast...

1) Is there no lesion? - or

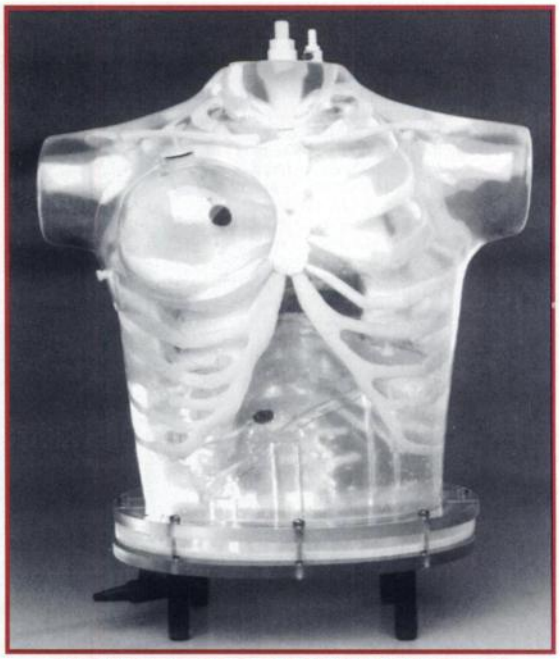
2) Is there a lesion that cannot be detected?

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[1], 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.



**STRIATAL PHANTOM**



**HEART/THORAX PHANTOM**

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.

[1]Evaluation of the Detectability of Breast Cancer Lesions Using a Modified Anthropomorphic Phantom. Niraj K. Doshi, Mario Basic and Simon R. Cherry. *Crump Institute for Biological Imaging and Department of Molecular and Medical Pharmacology. University of California at Los Angeles School of Medicine, Los Angeles; and Radiology Support Devices, Inc., Long Beach, California J. Nuclear Med. 1998: 39:1951-1957.*

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## 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 Signa 1.5T MR Imager, a GE Advance PET Scanner and a radiochemistry-cyclotron facility. In addition, research collaboration 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 aid in guiding the expansion of neuroscience research at the Center and will be instrumental in developing novel approaches to the study of brain activation and neurochemistry. Address application to: Dr. Mathis Frick, Chair, Department of Radiology, West Virginia University, HSC Box 9235, Morgantown, WV 26506-9235. Inquiries concerning the position should be made to Raymond Raylman, PhD at (304) 293-1973, e-mail: rraylman@wvu.edu. West Virginia University is an Equal Opportunity/Affirmative Action Employer.

**Nuclear Medicine/Radiology**

Respected, aggressive and innovative 32-person private practice Radiology group seeks highly qualified individual for Nuclear Medicine/Radiology position. Nuclear Medicine boarded or American Board of Radiology special competency strongly desired. Position includes all aspects of Nuclear Medicine, and the successful applicant will be encouraged to further develop this specialty throughout our large, diversified practice. We are situated in the beautiful Finger Lakes region of uptake 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-cu.com. EOE.

**Pediatric Nuclear Medicine Specialist–Québec**

The McGill University Health Centre (MUHC) invites application 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 Collège 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. Ó 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: aogomi@mch.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
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Director, Nuclear Medicine
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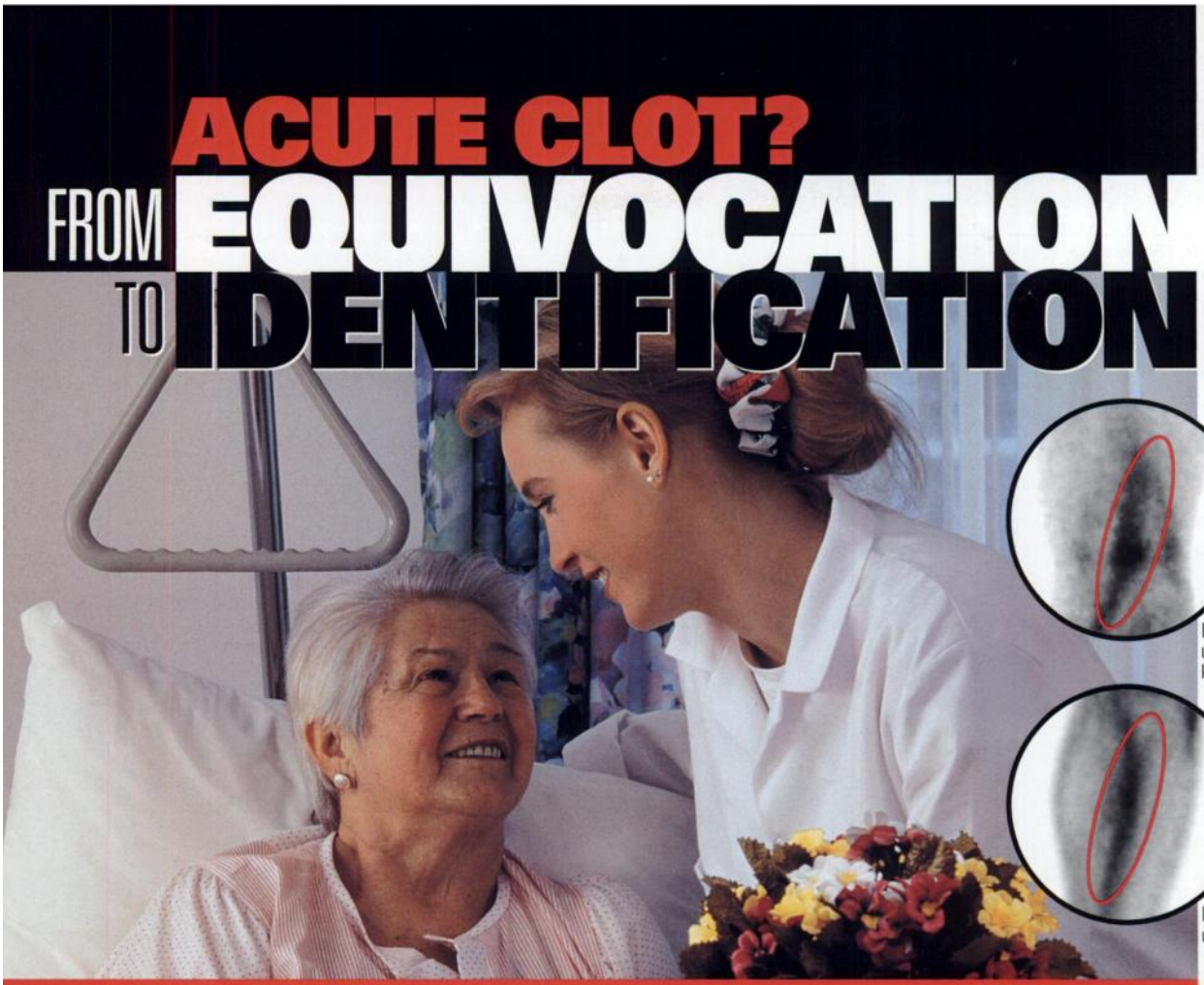
# ACUTE CLOT?
# FROM EQUIVOCATION TO IDENTIFICATION





Increased **tracer** uptake at knee/popli**teal vein**



Increased **tracer** uptake in **left calf**

## NEW

# ACUTECT™

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

## The first imaging modality to target *acute* DVT

AcuTect–a new, unique, radiolabeled synthetic peptide[1]–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.[1] AcuTect binds preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets.[1,2] AcuTect appears to detect acute and not chronic venous thrombosis. This is based on in vivo and ex vivo animal data; not confirmed clinically.[1] 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.

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Please see brief summary of prescribing information on following page.

# NEW ACUTECT™
## (Kit for the Preparation of Technetium Tc 99m Apcitide Injection)

### BRIEF SUMMARY OF PRESCRIBING INFORMATION
Please consult Full Product Information before using.

### DESCRIPTION
AcuTect™, 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 µg of bibapcitide, 75 mg of sodium glucoheptonate dihydrate, 89 µg of stannous chloride dihydrate, 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 apcitide monomers. When sterile, nonpyrogenic Sodium Pertechnetate Tc 99m Injection in 0.9% 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:** 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.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** 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. A fully equipped emergency cart, or equivalent supplies and equipment, and personnel competent in recognizing and treating anaphylactic reactions should be available. (See Adverse Reactions Section.)

### PRECAUTIONS
***General***

The contents of AcuTect™ Kit are intended only for use in the preparation of technetium Tc 99m apcitide, and are not to be administered to the patient without reconstitution.

Hypersensitivity: Small peptides may be immunogenic. Of 642 patients observed for 3 hours after AcuTect™ injection and of whom 169 were monitored for 24 hours, one patient had acute hypotension that began within 10 minutes of injection and, over 60 minutes, progressed to a systolic pressure of 70 mm Hg.

In preliminary studies of IgG binding to apcitide by ELISA assay, IgG binding was not detected. Other measures of immune function (e.g., complement, immune complexes, lymphokines) have not been studied. In preclinical animal models, there was a reduction in the absolute or relative weight of the spleen. The clinical significance of the reduced splenic weight to immune function is not known.

Technetium Tc 99m apcitide, like other radioactive drugs, must be handled with care and appropriate safety measures should be taken to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with appropriate patient management.

Radiopharmaceutical agents 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 governmental agency authorized to license the use of radionuclides.

Urinary excretion of radioactivity occurs over about 24 hours (with 75% occurring during the first 8 hours). Special precautions, such as bladder catheterization, should be taken with incontinent patients to minimize the risk of radioactive contamination of clothing, bed linen, and the patient's environment. Studies have not been done to evaluate the need to adjust the dose of AcuTect™ in patients with renal impairment.

***Information for Patients***

To minimize the absorbed radiation dose to the bladder, adequate hydration should be encouraged to ensure frequent voiding during the first few hours after AcuTect™ injection. To help protect themselves and others in their environment, patients need to take the following precautions for 12 hours following injection. Whenever possible, a toilet should be used, rather than a urinal, and the toilet should be flushed several times after each use. Spilled urine should be cleaned up completely. Patients should wash their hands thoroughly after each voiding. If blood or urine gets onto clothing, the clothing should be washed separately.

***Laboratory Tests***

AcuTect™ has been shown to inhibit platelet aggregation. The effect of AcuTect™ on bleeding time in humans has not been studied.

Moderate elevations in liver enzymes were noted in rare cases at three hours and persisted to at least 24 hours following administration of AcuTect™.

***Drug Interactions***

Clinically detectable drug interactions were not seen or explicitly studied in patients who received technetium Tc 99m apcitide and other concomitant medications. The effect of drugs that increase or decrease prothrombin time on the binding of AcuTect™ to activated platelets has not been studied.

The effect of heparin, warfarin, or aspirin on apcitide binding has not been studied in humans. In animal in vitro and ex vivo models, heparin or aspirin did not change the inhibition of platelet aggregation caused by apcitide. Whether heparin or aspirin change the ability of apcitide to bind to GPIIb/IIIa receptors on activated platelets was not studied. The effect of the duration of anticoagulation on apcitide binding was not studied.

***Carcinogenesis, Mutagenesis, Impairment of Fertility***

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. AcuTect™ was not mutagenic in the Ames test or mouse lymphoma test, and it was not clastogenic in the mouse micronucleus test.

***Pregnancy***

Pregnancy Category C. Animal reproduction studies have not been conducted with technetium Tc 99m apcitide. It is not known whether technetium Tc 99m apcitide or the other peptide components of the formulation can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m apcitide should be given to a pregnant woman only if clearly needed. Studies in pregnant women have not been conducted.

***Nursing Mothers***

Technetium Tc 99m pertechnetate is excreted in human milk. It is not known whether technetium Tc 99m apcitide is excreted in human milk. Caution should be exercised when technetium Tc 99m apcitide is administered to nursing women. Wherever possible, infant formula should be substituted for breast milk until the technetium has been eliminated.

***Pediatric Use***

Safety and effectiveness in pediatric patients have not been established.

### 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 µg of bibapcitide. Of these adults, 46% were women and 54% men. The mean age was 57.0 years (17 to 95 years). In all patients, adverse events were monitored for at least 3 hours. In a subset of 169 patients, adverse events were monitored for 24 hours. Deaths did not occur during the clinical study period. Following injection of technetium Tc 99m apcitide, a serious episode of hypotension occurred in one patient who had acute hypotension that began within 10 minutes of injection and, over 60 minutes, progressed to a systolic pressure of 70 mm Hg.

At least one adverse event occurred in 29/642 (4.5%) of patients after technetium Tc 99m apcitide injection. Pain was the most commonly reported adverse event ( 1.7% of patients or healthy volunteers). Table 1 lists adverse events reported in 0.5% or more of patients who received technetium Tc 99m apcitide.

**Table 1: Adverse Events Reported in ≥0.5 % of Patients Following AcuTect™ Injection in Clinical Studies**

| | |
|---|---|
| Number of Patients Exposed to AcuTect™ | 642 |
| Number of Patients with at Least One Adverse Event | 29 (4.5%) |
| Body as a Whole | 21 (3.3%) |
| Pain (back, leg, chest) | 11 (1.7%) |
| Headache | 5 (0.8%) |
| Cardiovascular System | 13 (2.0%) |
| Hypotension | 5 (0.8%) |
| Hypertension | 3 (0.5%) |

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

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

**DOSAGE AND ADMINISTRATION:** To detect acute venous thrombosis in a lower extremity, reconstituted AcuTect™ should be administered as a peripheral intravenous injection in an upper extremity, at a dose of approximately 100 µg of bibapcitide radiolabeled with 20 mCi of technetium 99m.

Technetium Tc 99m apcitide should be drawn into the syringe and administered using sterile technique. If nondisposable equipment is used, scrupulous care should be taken to prevent residual contamination with traces of cleansing 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 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 reinjection. The safety of more than one dose has not been studied.

Positive AcuTect™ uptake in the deep venous structures is defined as asymmetric vascular uptake (with or without superimposed diffuse 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 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 apcitide are listed in Table 2. The values are listed in descending order as rad/mCi and mGy/MBq and assume urinary bladder emptying at 4.8 hours.

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

| Target Organ | rad/mCi | mGy/MBq |
|---|---|---|
| Urinary Bladder Wall | 0.22 | 0.060 |
| Kidneys | 0.050 | 0.014 |
| Upper Large Intestine Wall | 0.039 | 0.010 |
| Lower Large Intestine Wall | 0.037 | 0.010 |
| Uterus | 0.034 | 0.0092 |
| Thyroid Gland | 0.022 | 0.0060 |
| Testes/Ovaries | 0.020/0.023 | 0.0053/0.0063 |
| Lungs | 0.016 | 0.0043 |
| Red Marrow | 0.0091 | 0.0025 |
| Breasts | 0.0050 | 0.0013 |

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 18, 1-4, 1988) and gave a value of 0.0093mSv/MBq (0.0034 rem/mCi).

### HOW SUPPLIED
Each kit contains one vial containing a sterile, nonpyrogenic, freeze-dried mixture of bibapcitide, 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). Store the reconstituted 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.
9 Delta Drive, Londonderry, New Hampshire 03053

Rev. September 1998
Distributed by: Diatide, Inc. and Nycomed Amersham
60-801971



**References: 1.** AcuTect Prescribing Information. **2.** Becker RC. Antiplatelet therapy. *Science & Medicine.* July/August 1996:12-21.

**The difference is acute.**

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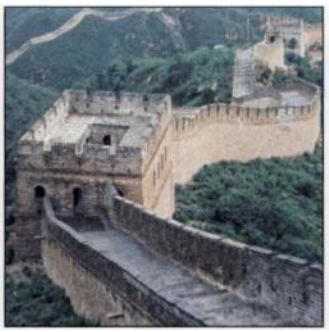
# The test of time.

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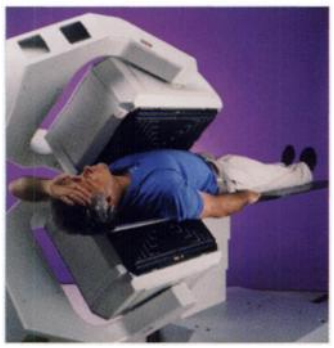

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