

# SIEMENS

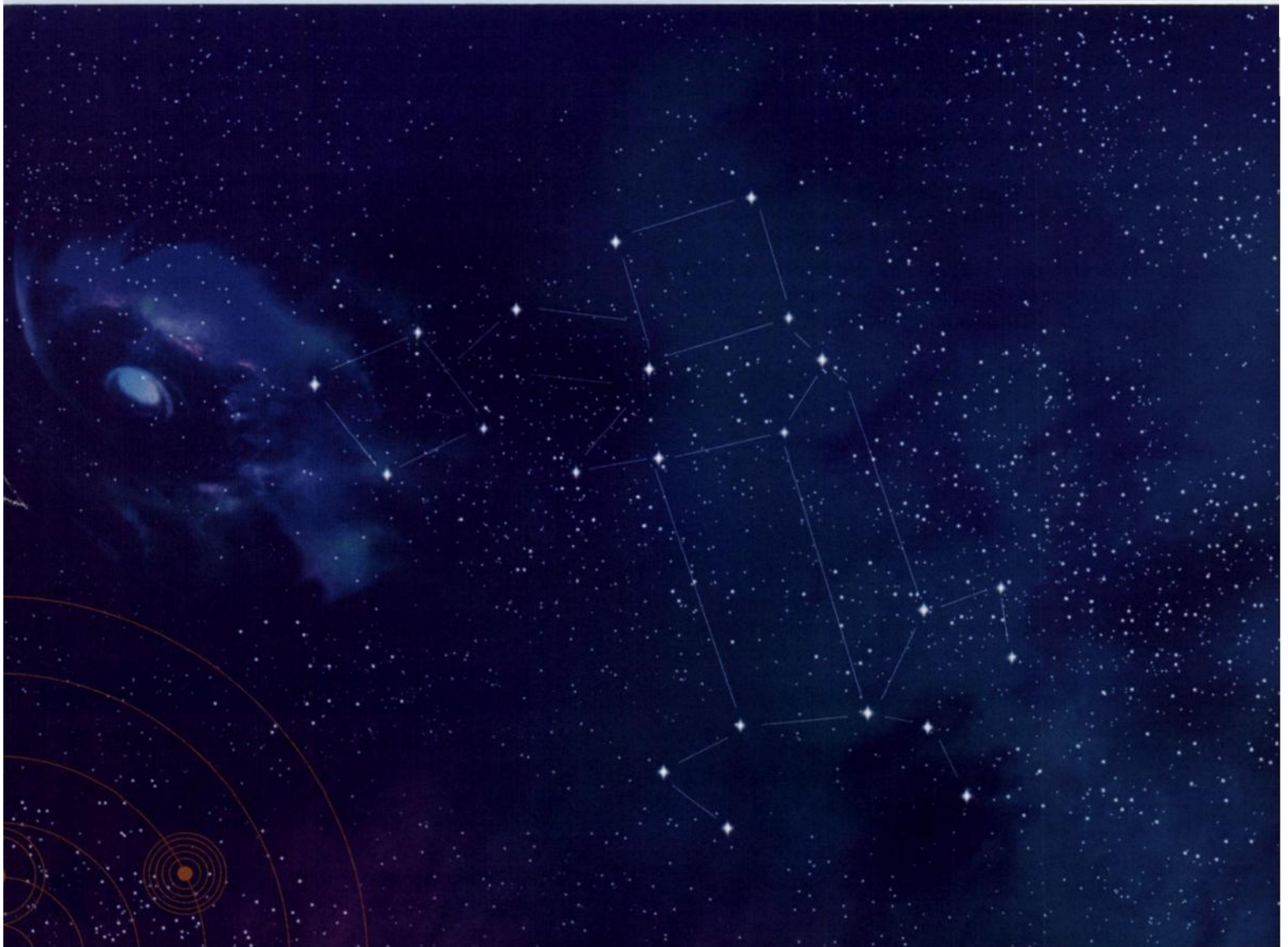
The E.CAM offers extensive cardiac-specific assessment tools that increase clinical quality and accuracy. The result...an unsurpassed level of clinical confidence.

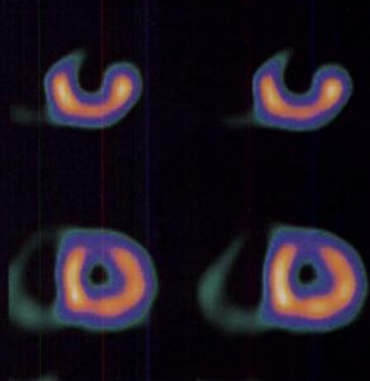
Featuring unique clinical solutions...

- Profile non-uniform attenuation correction
- Efficient comprehensive review displays

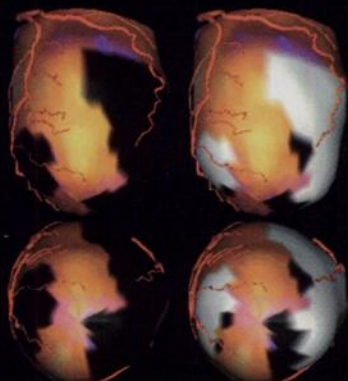
- Emory cardiac quantitative 'toolbox'
  - EF, volumes and mass
  - Wall motion analysis
  - Defect extent/reversibility maps
  - Transient ischemic dilatation ratio
  - 3D cardiac displays
  - Coronary artery overlays/image fusion

## *511 keV/PET Protection...*

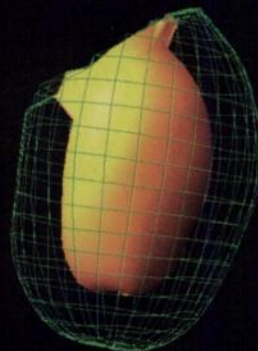




Profile Attenuation Correction



Emory Cardiac Toolbox



Cedars Gated SPECT Quantification

# ology

Siemens **medical**  
**Solutions** that help

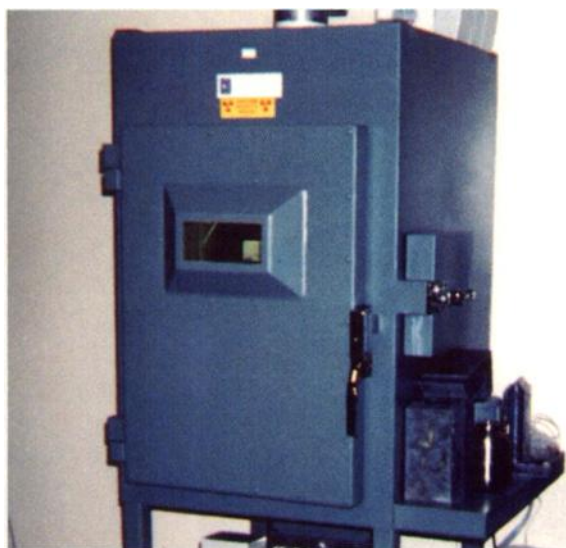


# *511 keV/PET Protection...*

## **Capintec is the Solution.**

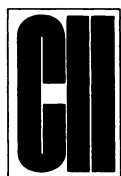
As growth in the use of high-energy radionuclides expands, Capintec has grown to meet your safety requirements.

### *CAPCELL® Mini-Cell*



- Ideal for all manufacturers radio-synthesis systems.
- "Top-of-the-line" Mini houses one of the larger FDG Systems.
- Optionally, "The Clean Air System" consists of a HEPA and/or Dacron filters for the intake air supply and, if required, a filtered exhaust.

*For more information call 800-275-4272*



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FAX: (201) 825-4829  
HOME PAGE: [www.capintec.com](http://www.capintec.com)

### *Capintec's Shielded Hoods*



- Laminar Flow and Radioisotope Fume Hoods available.
- Shown is a dual system (one shielded and one unshielded).
- Also shown is Capintec's "Body Shield" which moves between the two hoods.
- Capintec provides shielding to meet your customers requirements from 1 1/4" up to 3", as needed.


Visit the **Capintec** booth at the SNM Meeting in Los Angeles, where we will have on display a **new Spring-Arm Dose Dispensing System**. The same Spring-Arm design used on our CAPTUS® systems makes positioning the heavy-lead vial virtually effortless, while giving you maximum protection.

**Capintec** has developed valuable **new** tools for safely preparing patient doses...

*...Designed with the safety and convenience of our user in mind.*

**SNM Annual Meeting Booth # 157**

Circle Reader Service No. 23



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long imagined for  
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Digirad introduces the world's first solid-state planar and SPECT gamma camera, the 2020tc Imager™. Rising above the limitations of traditional technology, Nuclear Medicine's new star elevates the standards for image quality, clinical utility and performance reliability.

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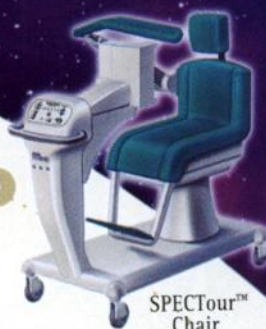
**Day,** Imagine a future where these advantages team

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# FIRST STEP TO INVENTING IT

SNM Annual Meeting Booth #119

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DuPont Pharmaceuticals Company  
Medical Imaging

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When the stress EKG is nondiagnostic in women  
or other challenging patients...

# “Now what?”

Order Cardiolite® to minimize false-positives,<sup>1,2</sup> and  
your decision becomes clear.



Normal Scan  
Short Axis



Abnormal Scan  
Short Axis  
Inferolateral Wall  
Defect

You want to know what's next. So does she. With Cardiolite®, you get perfusion *and* left ventricular function in a single, noninvasive test<sup>3,4</sup> for actionable, clinically relevant information to help you decide how to proceed.

A gated SPECT study with Cardiolite® enhances diagnostic specificity and provides functional information to optimize the detection of CAD in women<sup>1,2</sup> and in other patients who are challenging to image.<sup>5,6</sup> That's because a single Cardiolite® study provides information on the presence of preserved wall thickening and normal wall motion. It also helps to overcome artifacts caused by the breast and diaphragm<sup>1,2</sup>—minimizing false-positives or equivocal results by clearly distinguishing breast attenuation from true cardiac defects.<sup>1,2</sup>

Diagnostic accuracy is just the beginning. If her stress study with Cardiolite® is *normal*, you can even tell her there's a very low chance she'll have a serious cardiac event in the next year<sup>7,8</sup>—an answer she'll find very reassuring.

That's the kind of clear, reliable, and reproducible information you need to make patient management decisions with confidence. So, when her EKG is nondiagnostic, order Cardiolite®. It clears your line of vision.

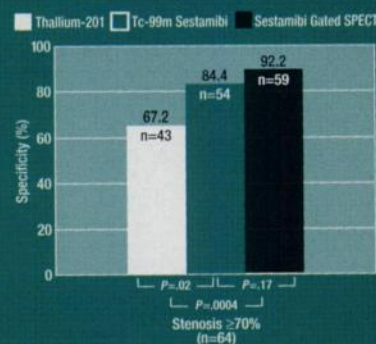
For more information contact us at 1-800-343-7851 or [www.cardiolite.com](http://www.cardiolite.com)

There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi.

\*This includes patients with large, dense breasts; COPD; narrow intercostal space; or mixed ischemia and scar; as well as those who are obese, are unable to exercise, or have nondiagnostic EKGs. Please see brief summary of prescribing information on the following page.

References: 1. Taillefer R et al. *J Am Coll Cardiol*. 1997;29:69-77. 2. DePuey EG et al. *J Nucl Med*. 1995;36:952-955. 3. Nichols K et al. *J Nucl Cardiol*. 1996;3:475-482. 4. Chua T et al. *J Am Coll Cardiol*. 1994;23:1107-1114. 5. Verani MS. *J Nucl Cardiol*. 1994;1:399-414. 6. Kisslo J et al. *J Am Soc Echocardiogr*. 1996;8:S23. 7. Travin MI et al. *Am Heart J*. 1997;134:73-82. 8. Hochamowitch R et al. *J Am Coll Cardiol*. 1996;28:34-44.

Increase Specificity<sup>†</sup> With Gated SPECT  
Using Cardiolite®<sup>1</sup>



<sup>†</sup> Refers to diagnostic specificity, defined as the probability that, given the absence of disease, a normal test result excludes disease. Adapted with permission from Taillefer et al.<sup>1</sup>



## Cardiolite®

Kit for the Preparation of  
Technetium Tc99m Sestamibi for Injection

It clears your line of vision

# Cardiolite

Kit for the Preparation of  
Technetium Tc99m Sestamibi for Injection

**INDICATIONS AND USAGE:** Myocardial Imaging: CARDIOLITE<sup>®</sup>, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, 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<sup>®</sup> 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.

**Breast Imaging:** MIRALUMA<sup>™</sup>, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, is indicated for planar imaging as a second-line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass.

MIRALUMA<sup>™</sup> is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not an alternative to biopsy.

**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, arrhythmia, 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.

Technetium Tc99m Sestamibi has been rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symptoms developed on the second injection during CARDIOLITE<sup>®</sup> imaging. Patients who receive CARDIOLITE<sup>®</sup> or MIRALUMA<sup>™</sup> imaging are receiving the same drug. Caution should be exercised and emergency equipment should be available when administering Technetium Tc99m Sestamibi. Also, before administering either CARDIOLITE<sup>®</sup> or MIRALUMA<sup>™</sup>, patients should be asked about the possibility of allergic reactions to either drug.

## 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%

**Information for Patients:** CARDIOLITE<sup>®</sup> and MIRALUMA<sup>™</sup> are different names for the same drug. Patients should be advised to inform their health care provider if they had any allergic reaction to either drug or if they had an imaging study with either drug.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** In comparison with most other diagnostic technetium-labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5 rads/30 mCi at rest, 1.2 rads/30 mCi 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)]<sup>2+</sup>, 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 ( $\geq 20 \mu\text{g/mL}$ ), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. [Cu(MIBI)]<sup>2+</sup> did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg,  $> 600 \times$  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 the pediatric population have not been established.

**ADVERSE REACTIONS:** Adverse events were evaluated in 3741 adults who were evaluated in clinical studies. Of these patients, 3068 (77% men, 22% women, and 0.7% of the patient's genders were not recorded) were in cardiac clinical trials and 673 (100% women) in breast imaging trials. Cases of angina, chest pain, and death have occurred (see WARNINGS and PRECAUTIONS). Adverse events reported at a rate of 0.5% or greater after receiving Technetium Tc99m Sestamibi administration are shown in the following table:

Table 9. Selected Adverse Events Reported in  $> 0.5\%$  of Patients Who Received Technetium Tc99m Sestamibi in Either Breast or Cardiac Clinical Studies\*

Body System	Breast Studies		Cardiac Studies	
	Women N = 673	Women N = 685	Men N = 2361	Total N = 3046
Body as a Whole	21 (3.1%)	6 (0.9%)	17 (0.7%)	23 (0.8%)
Headache	11 (1.6%)	2 (0.3%)	4 (0.2%)	6 (0.2%)
Cardiovascular	9 (1.3%)	24 (3.5%)	75 (3.2%)	99 (3.3%)
Chest Pain/Angina	0 (0%)	18 (2.6%)	46 (1.9%)	64 (2.1%)
ST Segment Changes	0 (0%)	11 (1.6%)	29 (1.2%)	40 (1.3%)
Digestive System	8 (1.2%)	4 (0.6%)	9 (0.4%)	13 (0.4%)
Nausea	4 (0.6%)	1 (0.1%)	2 (0.1%)	3 (0.1%)
Special Senses	132 (19.6%)	62 (9.1%)	160 (6.8%)	222 (7.3%)
Taste Perversion	129 (19.2%)	60 (8.8%)	157 (6.6%)	217 (7.1%)
Parosmia	8 (1.2%)	6 (0.9%)	10 (0.4%)	16 (0.5%)

\*Excludes the 22 patients whose genders were not recorded.

In the clinical studies for breast imaging, breast pain was reported in 12 (1.7%) of the patients. In 11 of these patients the pain appears to be associated with biopsy/surgical procedures.

The following adverse reactions have been reported in  $\leq 0.5\%$  of patients: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis; angioedema, arrhythmia, dizziness, syncope, abdominal pain, vomiting, and severe hypersensitivity characterized by dyspnea, hypotension, bradycardia, asthma, and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi. A few cases of flushing, edema, injection site inflammation, dry mouth, fever, pruritus, rash, urticaria and fatigue have also been attributed to administration of the agent.

**DOSAGE AND ADMINISTRATION:** For Myocardial Imaging: The suggested dose range for I.V. administration of CARDIOLITE<sup>®</sup> in a single dose to be employed in the average patient (70 kg) is 370 to 1110 MBq (10 to 30 mCi).

For Breast Imaging: The recommended dose range for I.V. administration of MIRALUMA<sup>™</sup> is a single dose of 740 to 1110 MBq (20 to 30 mCi).

**Image Acquisition: Breast Imaging:** It is recommended that images are obtained with a table overlay to separate breast tissue from the myocardium and liver, and to exclude potential activity that may be present in the opposite breast. For lateral images, position the patient prone with the ipsilateral arm comfortably above the head, shoulders flat against the table, head turned to the side and relaxed, with the breast imaged pendulous through an overlay cutout. The breast should not be compressed on the overlay. For anterior images, position the patient supine with both arms behind the head. For either lateral or anterior images, shield the chest and abdominal organs, or remove them from the field of view.

For complete study, sets of images should be obtained five minutes after the injection, and in the following sequence: Beginning five minutes after the injection of Technetium Tc99m Sestamibi:

- ten-minute lateral image of breast with abnormality
- ten-minute lateral image of contralateral breast
- ten-minute anterior image of both breasts

**RADIATION DOSIMETRY:** The radiation doses to organs and tissues of an average patient (70 kg) per 1110 MBq (30 mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 10.

Table 10. Radiation Absorbed Doses From Tc99m Sestamibi  
Estimated Radiation Absorbed Dose

Organ	2.0 hour void		4.8 hour void	
	rads/ 30 mCi	mGy/ 1110 MBq	rads/ 30 mCi	mGy/ 1110 MBq
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

Organ	2.0 hour void		4.8 hour void	
	rads/ 30 mCi	mGy/ 1110 MBq	rads/ 30 mCi	mGy/ 1110 MBq
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	0.2	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, (423) 576-3449.

**DRUG HANDLING:** 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 to 25°C before and after reconstitution.

**HOW SUPPLIED:** DuPont Pharmaceuticals' CARDIOLITE<sup>®</sup>, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, is supplied as a 5-mL vial in kits of two (2) (NDC # 11994-001-52); five (5) (NDC # 11994-001-55); and thirty (30) vials (NDC # 11994-001-58), sterile and non-pyrogenic.

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

This reagent kit is approved for distribution to persons licensed pursuant to the Code of Massachusetts Regulations 106 CMR 120.500 for the uses listed in 106 CMR 120.533 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, Agreement States or Licensing States.

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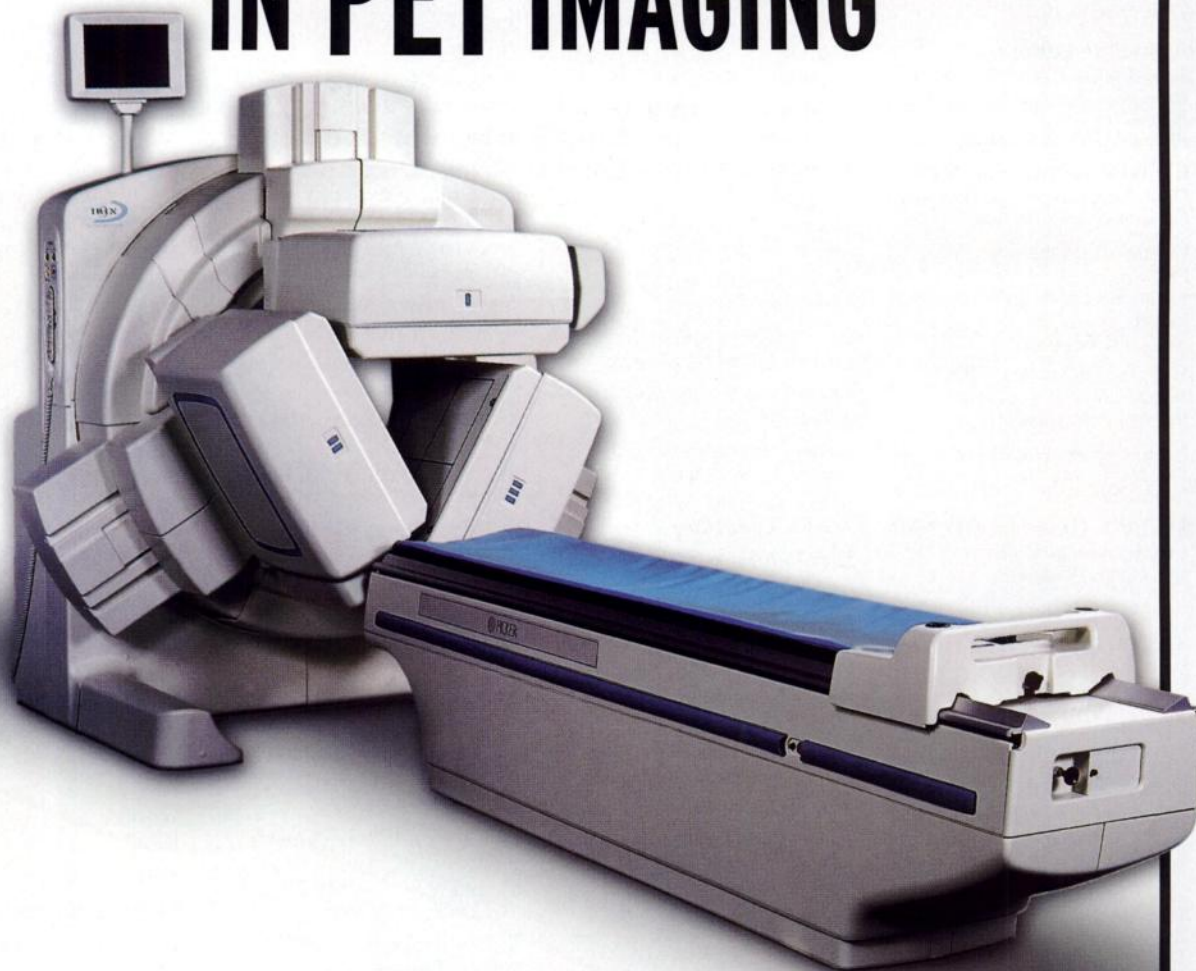
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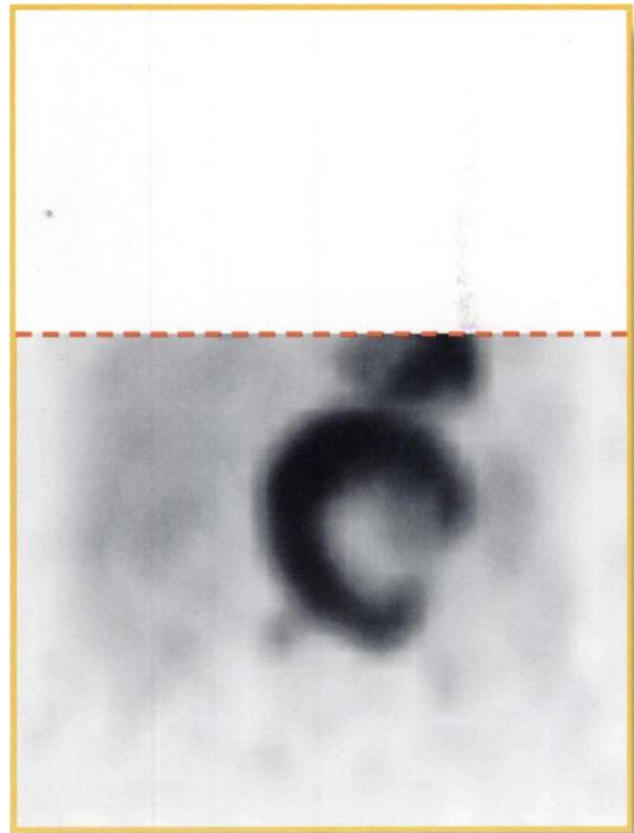
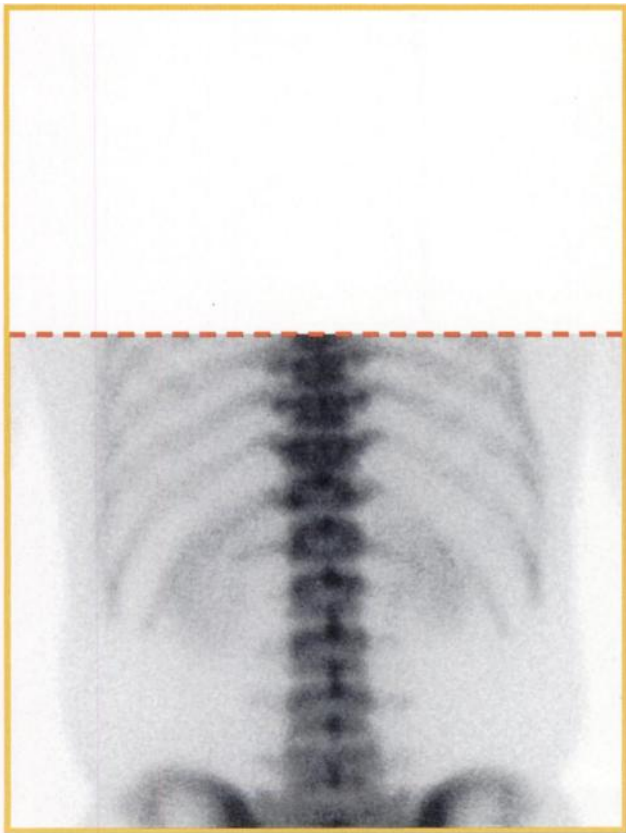
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Catch us at the SNM in Los Angeles in booth 327

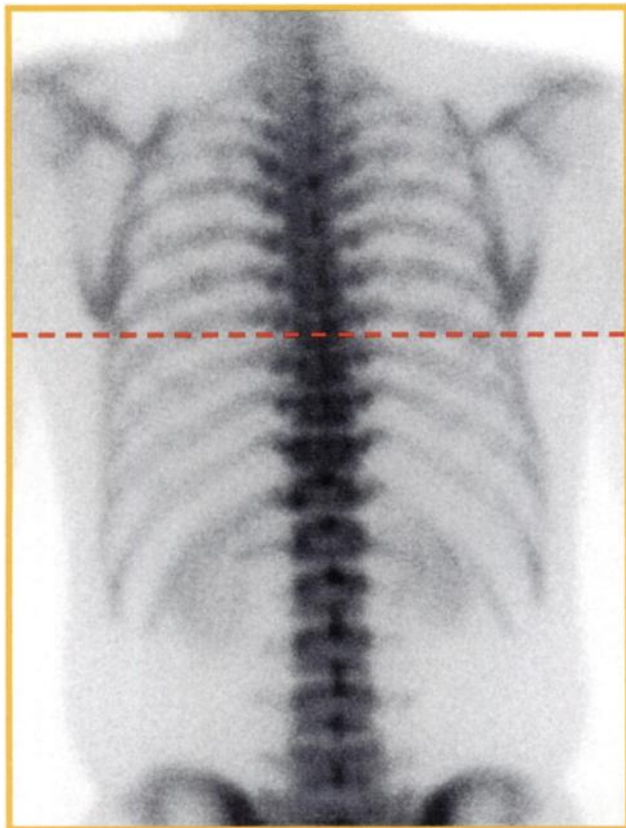
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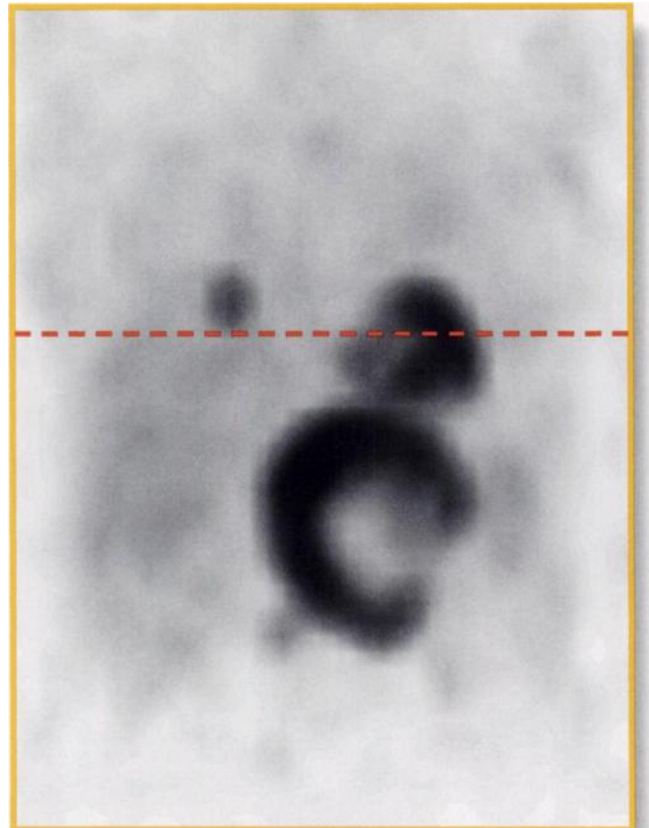
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**40% more**  
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*Normal bone scan demonstrating greater long axis coverage and excellent image quality.*



*VCR™ FDG coincidence image of a large necrotic tumor in the left lobe of the liver and small metastases in the mediastinum.*



When it comes to giving you the longest viewing area, no other camera comes close to matching the DST-XLi. Its 54.0cm (21.3 inch) FOV and unique long axis orientation delivers up to **40% more coverage from a single scan.** That covers the entire torso for most tomographic procedures - like bone metastasis or spinal evaluation - and is ideally suited for FDG coincidence imaging.

## More patients, Greater comfort



What's more, the DST-XLi delivers its **increased coverage in 50% less time.** Instead of requiring two complete scans to cover the entire torso - as with conventional short axis detector cameras - the DST-XLi does it in one. Think of the efficiency this will give your department. Not to mention the increased patient comfort from getting them off the table in half the time. **SANV**



# Get the **Big** picture



## DST-XLi

If you insist on making your diagnosis based on seeing the most information possible - but scanning patients twice to image the entire torso is more than your schedule and staff can handle - get the big picture with the DST-XLi. Not only do you get more information, you get image quality that is second to none. And, with the unique design of the DST-XLi, you will have

the flexibility to image patients in virtually any position. The detectors independently swivel to easily accommodate patients on any type of bed. Rotate the patient table 90 degrees and the 54.0cm long axis FOV becomes the premium single-pass whole body camera system you have always wanted. For more information on the DST-XLi and the many benefits you will enjoy, give us a call or visit our web site at <http://www.smvnet.com>.

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*The Nuclear Medicine Company*

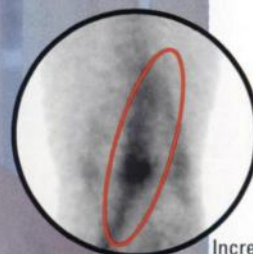
**SMVInternational**  
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Z.I. BP 112  
78534 Buc Cedex  
FRANCE  
Tel: 33.1.30.84.91.00  
Fax: 33.1.30.84.91.05



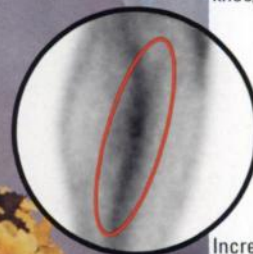
# ACUTE CLOT?

FROM  
TO

# EQUIVOCATION IDENTIFICATION



Increased tracer uptake at knee/popliteal vein



Increased tracer uptake in left calf

## ACUTECT<sup>™</sup>

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

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

AcuTect—a unique, radiolabeled synthetic peptide<sup>1</sup>—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.<sup>1</sup> AcuTect binds preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets.<sup>1,2</sup> AcuTect appears to detect acute and not chronic venous thrombosis. This is based on in vivo and ex vivo animal data; not confirmed clinically.<sup>1</sup> The result is a new sensitivity that challenges venography—the “gold standard.”

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

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

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

For customer service, call 1-877-DIATIDE.

**The difference is acute.**

 **Diatide, Inc.**

Please see brief summary of prescribing information on following page.

**WE'VE  
GOT YOUR  
SOLUTIONS.** **Nycomed  
Amersham**

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# 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 bipapcitide, 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.

Bipapcitide 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 bipapcitide 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 bipapcitide. 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, hypertension, 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 bipapcitide 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 bipapcitide, 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 20-25° 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  
80-4500010403

AcuTect™ is a trademark of Diatide, Inc.

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

# The difference is acute.

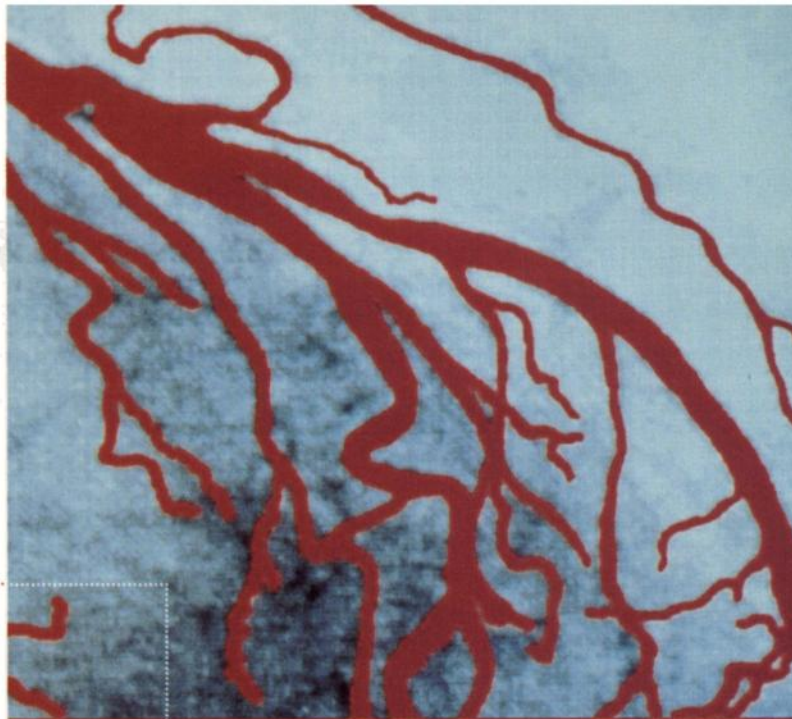
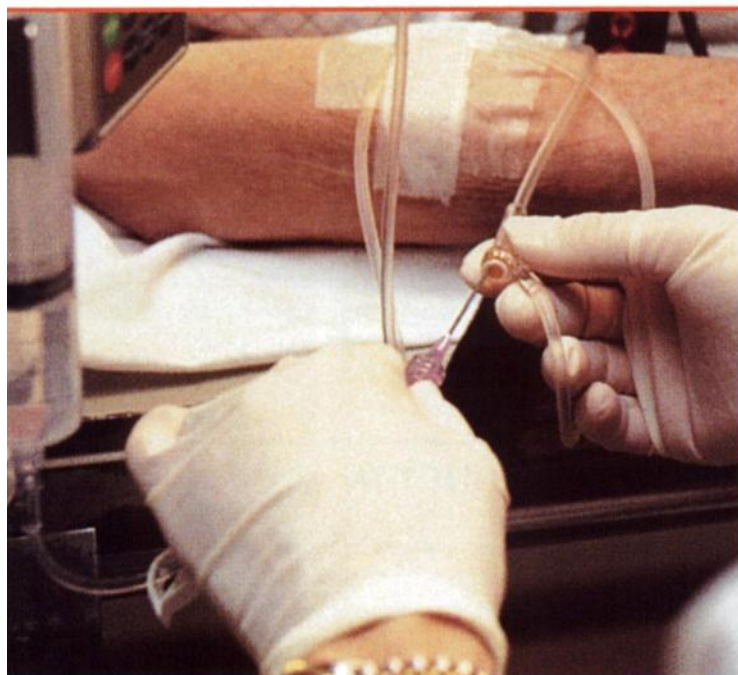
 **Diatide, Inc.**

**WE'VE GOT YOUR SOLUTIONS. Nycomed Amersham**

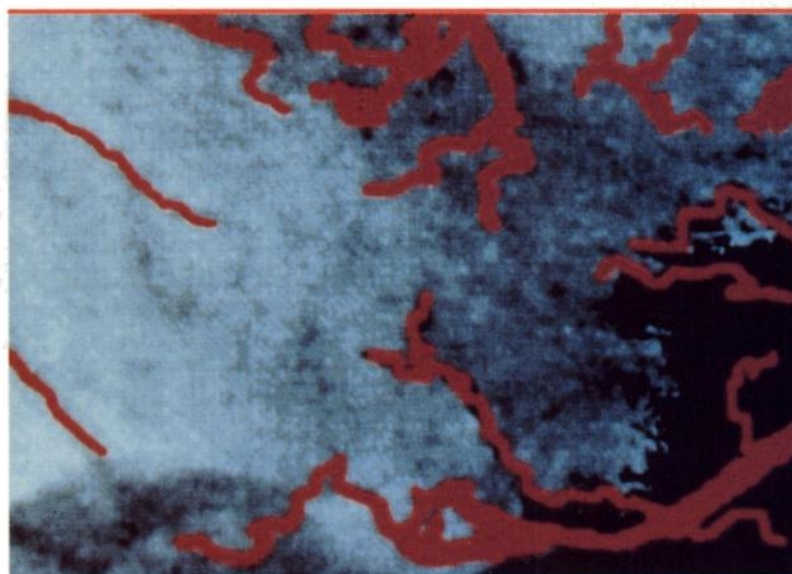




*fast* **START**



*wide* **OPEN**



*Where pharm stress should be  
from start to finish*

**FAST START**

- Onset of action is rapid and predictable.
- Maximum coronary hyperemia within 2-3 minutes in most cases.

**WIDE OPEN**

- Consistently produces maximal vasodilation.
- Blood flow increases 3- to 4-fold over baseline.<sup>1</sup>

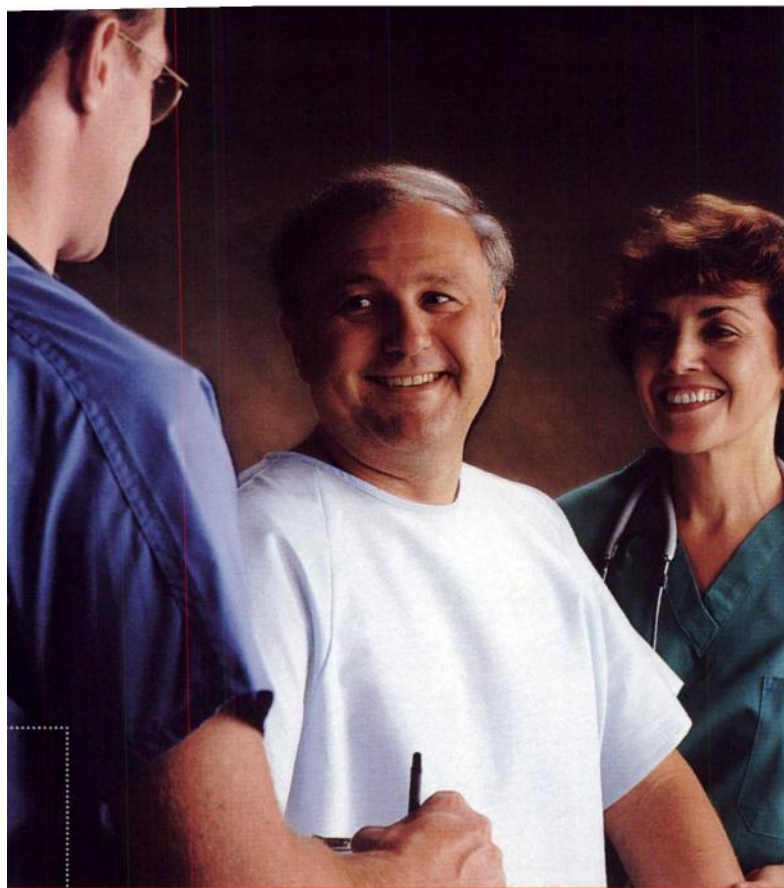
**RAPID RETURN**

- <10-second half-life.
- Side effects usually resolve quickly and spontaneously.\*

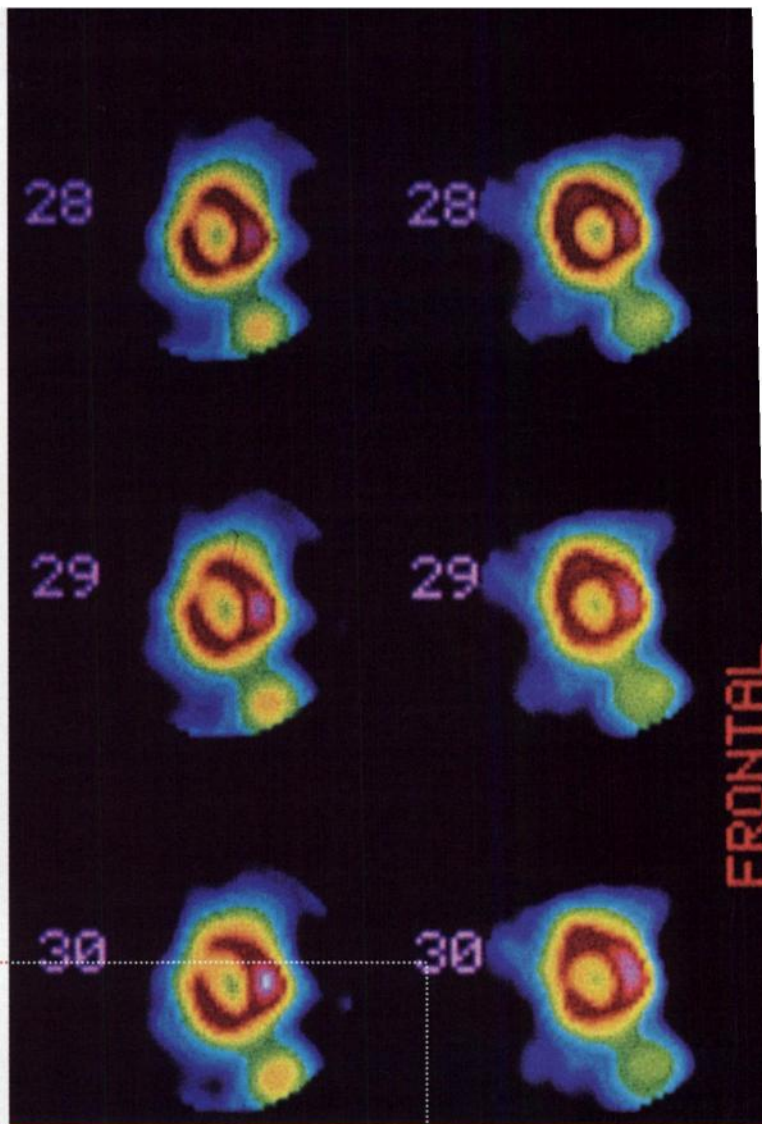
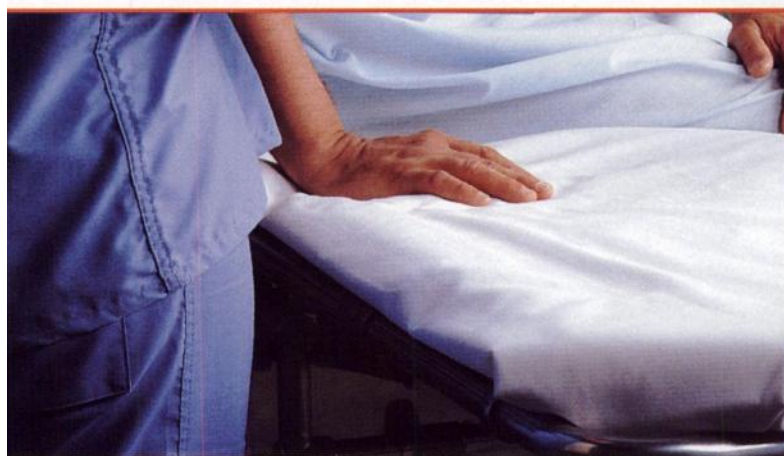
**STRONG FINISH**

- Imaging comparable to exercise.
- Lower cost-per-case than dipyridamole.<sup>2</sup>

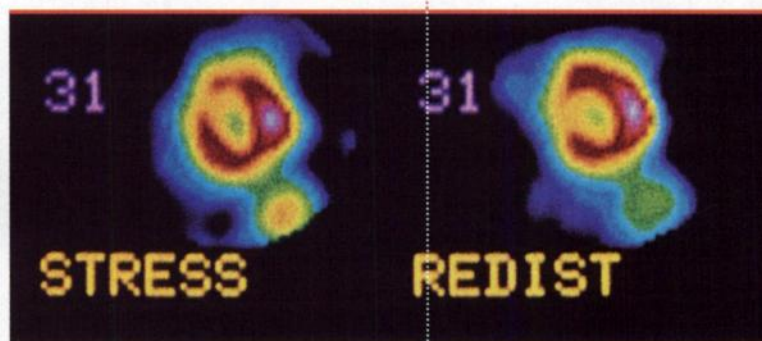




*rapid* RETURN



*strong* FINISH



\* Despite the short half-life, 10.6% of the side effects occurred not with the infusion of Adenoscan but several hours after infusion. Also, 8.4% of the side effects that began coincident with infusion persisted for up to 24 hours after infusion was completed. In many cases, it is not possible to know whether these late adverse events are the result of Adenoscan infusion.

Please see the brief summary of prescribing information on the following page.

**ADENOSCAN<sup>®</sup>**  
adenosine

Circle Reader Service No. 50

[www.adenoscan.com](http://www.adenoscan.com)



# THERE'S SOMETHING NEW ON THE WEB...

Visit this interactive new educational website dedicated to myocardial perfusion imaging. You'll find a wealth of information plus practical instruction in the principles and clinical applications of this important diagnostic modality.

## AN OVERVIEW OF MYOCARDIAL PERFUSION IMAGING

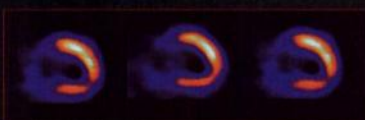
You'll find:

- a pictorial comparison of nuclear images with human anatomy
- an interactive exercise in image interpretation
- a comprehensive reference compilation

...all designed specifically for the medical professional: practicing physicians, medical education faculty, residents and students.

AVAILABLE NOW AT:

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**Fujisawa**

Fujisawa Healthcare, Inc.  
Deerfield, Illinois 60015

## ADENOSCAN® adenosine

### BRIEF SUMMARY

#### 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 (0.9%) 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 reflex mechanism are able to maintain blood pressure and tissue perfusion in response to Adenoscan by increasing heart rate and cardiac output. However, Adenoscan should be used with caution in patients with autonomic dysfunction, stenotic valvular heart disease, 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 (V<sub>E</sub>) and reduce arterial P<sub>CO</sub><sub>2</sub>, 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 dipyridamole (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<sup>2</sup> 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 have 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.

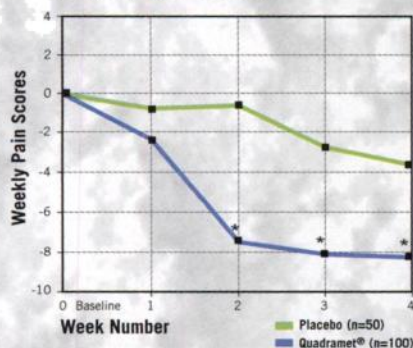
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**SNM Annual Meeting Booth #606**



### RAPID RESPONSE

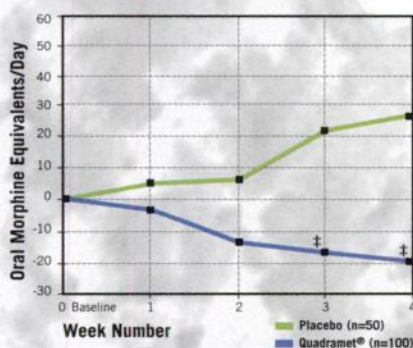
Change in weekly pain scores based on patient assessment<sup>1</sup>



\*Statistically significant difference from baseline vs. placebo.

### OPIOID REDUCTION

Mean change from baseline in daily opioid analgesic use<sup>1†</sup>



†Based on weekly mean of daily opioid use.

‡Statistically significant difference from baseline vs. placebo.

### REVERSIBLE AND PREDICTABLE MYELOSUPPRESSION

Bone marrow function recovers rapidly with Quadramet<sup>®</sup>; WBC and platelet counts decrease to a nadir of 40% to 50% of baseline within 3 to 5 weeks, and tend to return to pretreatment levels within 8 weeks.<sup>1</sup>

Before Quadramet<sup>®</sup> is administered, consideration should be given to the patient's current clinical and hematologic status and bone marrow response history to treatment with myelotoxic agents. Quadramet<sup>®</sup> causes bone marrow suppression.

Reference: 1. Prescribing information for Quadramet<sup>®</sup>.



## Bring quality to life

### RELIEVE BONE PAIN DUE TO CANCER WITH QUADRAMET<sup>®</sup>

For confirmed osteoblastic metastases in patients with prostate, breast, or other cancers, relieve bone pain with Quadramet<sup>®</sup>: the control *you* need, the relief *they* need.

Patients who respond to Quadramet<sup>®</sup> may begin to notice the onset of pain relief 1 week after administration.<sup>1</sup>

Quadramet<sup>®</sup> is a single-injection radiopharmaceutical treatment for bone pain in patients with osteoblastic metastases. Quadramet<sup>®</sup> is administered in a single out-patient visit. The individually tailored dose (1.0 mCi/kg) accumulates specifically in osteoblastic lesions.<sup>1</sup>

**Quadramet<sup>®</sup>**   
(Samarium Sm 153 Lexidronam Injection)

**www.quadramet.com • 1-888-BERLEX-4**

Quadramet is a registered trademark of the Dow Chemical Company. Please see brief summary of prescribing information on following page.

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## Brief Summary—Before Prescribing Consult Full Prescribing Information

**INDICATIONS:** Quadramet is indicated for relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on radionuclide bone scan.

**CONTRAINDICATIONS:** Quadramet is contraindicated in patients who have known hypersensitivity to EDTMP or similar phosphonate compounds.

**WARNINGS:** Quadramet causes bone marrow suppression. In clinical trials, white blood cell counts and platelet counts decreased to a nadir of approximately 40% to 50% of baseline in 123 (95%) of patients within 3 to 5 weeks after Quadramet, and tended to return to pretreatment levels by 8 weeks. The grade of marrow toxicity is shown in Table 5 below.

Table 5

Number and percent of patients who experienced marrow toxicity in clinical trials of Quadramet						
	Hemoglobin		Leucocytes		Platelets	
Toxicity Grade*	Placebo N = 85	1.0 mCi/kg N = 185	Placebo N = 85	1.0 mCi/kg N = 184	Placebo N = 85	1.0 mCi/kg N = 185
0-2	78 (92%)	162 (88%)	85 (100%)	169 (92%)	85 (100%)	173 (94%)
3	6 (7%)	20 (11%)	0 (0%)	15 (8%)	0 (0%)	10 (5%)
4	1 (1%)	3 (2%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)

Toxicity Grade based upon National Cancer Institute Criteria; normal levels are Hemoglobin >10g/dL, Leucocyte ≥4.0 x 10<sup>9</sup>/L, and Platelets ≥150,000/μL.

Before Quadramet is administered, consideration should be given to the patient's current clinical and hematologic status and bone marrow response history to treatment with myelotoxic agents. Metastatic prostate and other cancers can be associated with disseminated intravascular coagulation (DIC); caution should be exercised in treating cancer patients whose platelet counts are falling or who have other clinical or laboratory findings suggesting DIC. Because of the unknown potential for additive effects on bone marrow, Quadramet should not be given concurrently with chemotherapy or external beam radiation therapy unless the clinical benefits outweigh the risks. Use of Quadramet in patients with evidence of compromised bone marrow reserve from previous therapy or disease involvement is not recommended unless the potential benefits of the treatment outweigh the risks. Blood counts should be monitored weekly for at least 8 weeks, or until recovery of adequate bone marrow function.

**Pregnancy:** As with other radiopharmaceutical drugs, Quadramet can cause fetal harm when administered to a pregnant woman. Adequate and well controlled studies have not been conducted in animals or pregnant women. Women of child-bearing age should have a negative pregnancy test before administration of Quadramet. If this drug is used during pregnancy, or if a patient becomes pregnant after taking this drug, the patient should be apprised of the potential hazard to the fetus. Women of child-bearing potential should be advised to avoid becoming pregnant. Men and women patients should be advised to use an effective method of contraception after the administration of Quadramet.

**PRECAUTIONS:** EDTMP is a chelating agent. Although the chelating effects have not been evaluated thoroughly in humans, dogs that received non-radioactive samarium EDTMP (6 times the human dose based on body weight, 3 times based on surface area) developed a variety of electrocardiographic (ECG) changes (with or without the presence of hypocalcemia). The causal relationship between the hypocalcemia and ECG changes has not been studied. Whether Quadramet causes electrocardiographic changes or arrhythmias in humans has not been studied. Caution and appropriate monitoring should be given when administering Quadramet to patients (See Laboratory Tests).

Because concomitant hydration is recommended to promote the urinary excretion of Quadramet, appropriate monitoring and consideration of additional supportive treatment should be used in patients with a history of congestive heart failure or renal insufficiency.

This drug should be used with caution in patients with compromised bone marrow reserves. See Warnings.

**Skeletal:** Spinal cord compression frequently occurs in patients with known metastases to the cervical, thoracic or lumbar spine. In clinical studies of Quadramet, spinal cord compression was reported in 7% of patients who received placebo and in 8.3% of patients who received 1.0 mCi/kg Quadramet. Quadramet is not indicated for treatment of spinal cord compression. Quadramet administration for pain relief of metastatic bone cancer does not prevent the development of spinal cord compression. When there is a clinical suspicion of spinal cord compression, appropriate diagnostic and therapeutic measures must be taken immediately to avoid permanent disability.

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 government agency authorized to license the use of radionuclides.

Quadramet, like other radioactive drugs, must be handled with care, and appropriate safety measures must be taken to minimize radiation exposure of clinical personnel and others in the patient environment.

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. Urinary excretion of radioactivity occurs over about 12 hours (with 35% occurring during the first 6 hours). Studies have not been done on the use of Quadramet in patients with renal impairment.

**PREGNANCY:** Pregnancy Category D. See Warnings Section.

**NURSING MOTHERS:** It is not known whether Quadramet is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Quadramet, a decision should be made whether to continue nursing or to administer the drug. If Quadramet is administered, formula feedings should be substituted for breast feedings.

**PEDIATRIC USE:** Safety and effectiveness in pediatric patients below the age of 16 years have not been established.

**ADVERSE EVENTS:** Adverse events were evaluated in a total of 580 patients who received Quadramet in clinical trials. Of the 580 patients, there were 472 men and 108 women with a mean age of 66 (range 20 to 87).

Of these patients, 472 (83%) had at least one adverse event. In a subgroup of 399 patients who received Quadramet 1.0 mCi/kg, there were 23 deaths and 46 serious adverse events. The deaths occurred an average of 67 days (9 to 130) after Quadramet. Serious events occurred an average of 46 days (1 - 118) after Quadramet. Although most of the patient deaths and serious adverse events appear to be related to the underlying disease, the relationship of end stage disease, marrow invasion by cancer cells, previous myelotoxic treatment and Quadramet toxicity can not be easily distinguished. In clinical studies, two patients with rapidly progressive prostate cancer developed thrombocytopenia and died 4 weeks after receiving Quadramet. One of the patients showed evidence of disseminated intravascular coagulation (DIC); the other patient experienced a fatal cerebrovascular accident, with a suspicion of DIC. The relationship of the DIC to the bone marrow suppressive effect of Samarium is not known. Marrow toxicity occurred in 277 (47%) patients (See Warnings section).

In controlled studies, 7% of patients receiving 1.0 mCi/kg Quadramet (as compared to 6% of patients receiving placebo) reported a transient increase in bone pain shortly after injection (flare reaction). This was usually mild, self-limiting, and responded to analgesics.

The most common adverse events observed in controlled clinical studies of Quadramet, are given in Table 6 below.

Table 6

Selected adverse events reported in ≥ 1.0% of people who received Quadramet or placebo in controlled clinical trials

ADVERSE EVENT	Placebo N = 90	Quadramet 1.0 mCi/kg N = 199
# Patients with Any Adverse Event	72 (80%)	169 (85%)
Body As A Whole	56 (62%)	100 (50%)
Pain Flare Reaction	5 (5.6%)	14 (7.0%)
Cardiovascular	19 (21%)	32 (16%)
Arrhythmias	2 (2.2%)	10 (5.0%)
Chest Pain	4 (4.4%)	8 (4.0%)
Hypertension	0	6 (3.0%)
Hypotension	2 (2.2%)	4 (2.0%)
Digestive	44 (49%)	82 (41%)
Abdominal Pain	7 (7.8%)	12 (6.0%)
Diarrhea	3 (3.3%)	12 (6.0%)
Nausea &/or Vomiting	37 (41.1%)	65 (32.7%)
Hematologic & Lymphatic	12 (13%)	54 (27%)
Coagulation Disorder	0	3 (1.5%)
Hemoglobin Decreased	21 (23.3%)	81 (40.7%)
Leukopenia	6 (6.7%)	118 (59.3%)
Lymphadenopathy	0	4 (2.0%)
Thrombocytopenia	8 (8.9%)	138 (69.3%)
Any Bleeding Manifestations	8 (8.9%)	32 (16.1%)
Echymosis	1 (1.1%)	3 (3.0%)
Epistaxis	1 (1.1%)	4 (2.0%)
Hematuria	3 (3.3%)	10 (5%)
Infection	10 (11.1%)	34 (17.1%)
Fever and/or Chills	10 (11.1%)	17 (8.5%)
Infection NOS	4 (4.4%)	14 (7.0%)
Oral Moniliasis	1 (1.1%)	4 (2.0%)
Pneumonia	1 (1.1%)	3 (1.5%)
Musculoskeletal	28 (31%)	55 (27%)
Myasthenia	8 (8.9%)	13 (6.5%)
Pathologic Fracture	2 (2.2%)	5 (2.5%)
Nervous	39 (43%)	59 (30%)
Dizziness	1 (1.1%)	8 (4.0%)
Paresthesia	7 (7.8%)	4 (2.0%)
Spinal Cord Compression	5 (5.5%)	13 (6.5%)
Cerebrovascular Accident/Stroke	0	2 (1.0%)
Respiratory	24 (27%)	35 (18%)
Bronchitis/Cough Increased	2 (2.2%)	8 (4.0%)
Special Senses	11 (12%)	11 (6%)
Skin & Appendages	17 (19%)	13 (7%)
Purpura	0	2 (1%)
Rash	2 (2.2%)	2 (1%)

Includes hemorrhage (gastrointestinal, ocular) reported in <1%.

In an additional 200 patients who received Quadramet in uncontrolled clinical trials, adverse events that were reported at a rate of ≥1.0% were similar except for 9 (4.5%) patients who had agranulocytosis. Other adverse events that were reported in <1% of the patients who received Quadramet 1.0 mCi/kg in any clinical trial include: alopecia, angina, congestive heart failure, sinus bradycardia, and vasodilation.

**OVERDOSAGE:** Overdosage with Quadramet has not been reported. An antidote for Quadramet overdosage is not known. The anticipated complications of overdosage would likely be secondary to bone marrow suppression from the radioactivity of <sup>153</sup>Sm, or secondary to hypocalcemia and cardiac arrhythmias related to the EDTMP.

**DOSEAGE AND ADMINISTRATION:** The recommended dose of Quadramet is 1.0 mCi/kg, administered intravenously over a period of one minute through a secure in-dwelling catheter and followed with a saline flush. Dose adjustment in patients at the extremes of weight have not been studied. Caution should be exercised when determining the dose in very thin or very obese patients.

The dose should be measured by a suitable radioactivity calibration system, such as a radioisotope dose calibrator, immediately before administration.

The radioactive dose to be administered and the patient should be verified before administering Quadramet. Patients should not be released until their radioactivity levels and exposure rates comply with federal and local regulations.

The patient should ingest (or receive by i.v. administration) a minimum of 500 mL (2 cups) of fluids prior to injection and should void as often as possible after injection to minimize radiation exposure to the bladder.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. The solution should not be used if it is cloudy or if it contains particulate matter.

Quadramet contains calcium and may be incompatible with solutions that contain molecules that can complex with and form calcium precipitates.

Quadramet should not be diluted or mixed with other solutions.

Thaw at room temperature before administration and use within 8 hours of thawing.

# RAPID CLEARANCE IN CARDIAC NUCLEAR IMAGING



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Technetium Tc99m Tetrofosmin For Injection

**Increase patient throughput—with rapid  
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Give your nuclear department "rapid clearance" capability with MYOVIEW. MYOVIEW clears quickly from the blood, liver, and lungs<sup>1-3</sup> for quality target-to-background ratios and timely imaging (as soon as 15 minutes or up to 4 hours post-injection).<sup>1</sup> The clearance properties of MYOVIEW allow for highly flexible camera scheduling and enhanced patient management. Any way you look at it, you're cleared for efficiency with MYOVIEW.

MYOVIEW is not indicated for use with pharmacologic stress agents.

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.

Please see Brief Summary of Prescribing Information on adjacent page.

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**References:** 1. Sridhara BS, Braat S, Rigo P, et al. Comparison of myocardial perfusion imaging with technetium-99m tetrofosmin versus thallium-201 in coronary artery disease. *Am J Cardiol.* 1993;72(14):1015-1019. 2. Higley B, Smith FV, Smith T, et al. Technetium-99m-1,2-bis[bis(2-ethoxyethyl)phosphino]ethane: human biodistribution, dosimetry and safety of a new myocardial perfusion imaging agent. *J Nucl Med.* 1993;34(1):30-38. 3. Kelly JD, Forster AM, Higley B, et al. Technetium-99m-tetrofosmin as a new radiopharmaceutical for myocardial perfusion imaging. *J Nucl Med.* 1993;34(2):222-227.

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**MYOVIEW™**

Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection

BS-43-1011

Diagnostic Radiopharmaceutical for intravenous use only  
Code N186A

**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 predispensed, sterile, non-pyrogenic, lyophilized mixture of 0.23 mg tetrofosmin [6,9-bis(2-ethoxyethyl)-3,12-dioxo-6,9-diphosphatetetrade-cane], 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-glucuronate, 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 29-94 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 Absorbed Radiation Doses**  
**(Technetium Tc99m Tetrofosmin Injection)**

Target organ	Absorbed radiation dose			
	Exercise		Rest	
	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, 1978). Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4), 1988) and gave values of  $8.61 \times 10^{-4}$  mSv/MBq and  $1.12 \times 10^{-4}$  mSv/MBq after exercise and rest, respectively.

Manufactured by Amersham International plc  
Amersham, United Kingdom

Patent No. 5,045,302 (r)

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### Guiding you to optimal intervention for neuroendocrine tumors

- Somatostatin receptor scintigraphy with OctreoScan detects and localizes primary tumors and metastatic spread often missed by conventional imaging (sensitivity varies 61%-100%, depending on tumor type).<sup>1</sup>
- Whole-body scanning can more definitively confirm the extent of disease.
- You are better able to
  - stage the patient
  - determine diagnostic work-up
  - avoid unnecessary procedures
  - select optimal treatment
  - assess surgical candidates
  - evaluate response to treatment
- Transient adverse effects including dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness were observed in less than 1% of 538 patients during clinical trials.
- Please see the prescribing information for special considerations regarding patients receiving total parenteral nutrition or concurrent octreotide acetate therapy and patients with insulinoma or impaired renal function.

*The accepted standard  
for GEP\* tumors*

*An emerging choice for  
small cell lung cancer*

\*Gastroentero-pancreatic neuroendocrine tumors



**OCTREOSCAN®**

Kit for the Preparation of Indium In-111 Pentetreotide

SNM Annual Meeting Booth #315

Please see adjacent page for brief summary of prescribing information.



# OCTREOSCAN<sup>®</sup>

## Kit for the Preparation of Indium In-111 Pentetreotide

### BRIEF SUMMARY OF PRESCRIBING INFORMATION

#### DESCRIPTION

OctreoScan<sup>®</sup> is a kit for the preparation of indium In-111 pentetreotide, a diagnostic radio-pharmaceutical. It is a kit consisting of two components:

- 1) A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of 10 µg pentetreotide.
- 2) A 10-mL vial of Indium In-111 Chloride Sterile Solution.

Indium In-111 pentetreotide is prepared by combining the two kit components.



#### INDICATIONS AND USAGE

Indium In-111 pentetreotide is an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors.

#### CONTRAINDICATIONS

None known.

#### WARNINGS

DO NOT ADMINISTER IN TOTAL PARENTERAL NUTRITION (TPN) ADMIXTURES OR INJECT INTO TPN INTRAVENOUS ADMINISTRATION LINES; IN THESE SOLUTIONS, A COMPLEX GLYCOSYL OCTREOTIDE CONJUGATE MAY FORM.

The sensitivity of scintigraphy with indium In-111 pentetreotide may be reduced in patients concurrently receiving therapeutic doses of octreotide acetate. Consideration should be given to temporarily suspending octreotide acetate therapy before the administration of indium In-111 pentetreotide and to monitoring the patient for any signs of withdrawal.

#### PRECAUTIONS

##### General

1. Therapy with octreotide acetate can produce severe hypoglycemia in patients with insulinomas. Since pentetreotide is an analog of octreotide, an intravenous line is recommended in any patient suspected of having an insulinoma. An intravenous solution containing glucose should be administered just before and during administration of indium In-111 pentetreotide.
2. The contents of the two vials supplied with the kit are intended only for use in the preparation of indium In-111 pentetreotide and are NOT to be administered separately to the patient.
3. Since indium In-111 pentetreotide is eliminated primarily by renal excretion, use in patients with impaired renal function should be carefully considered.
4. To help reduce the radiation dose to the thyroid, kidneys, bladder, and other target organs, patients should be well hydrated before the administration of indium In-111 pentetreotide. They should increase fluid intake and void frequently for one day after administration of this drug. In addition, it is recommended that patients be given a mild laxative (e.g., bisacodyl or lactulose) before and after administration of indium In-111 pentetreotide (see Dosage and Administration section).
5. Indium In-111 pentetreotide should be tested for labeling yield of radioactivity prior to administration. The product must be used within six hours of preparation.
6. Components of the kit are sterile and nonpyrogenic. To maintain sterility, it is essential that directions are followed carefully. Aseptic technique must be used during the preparation and administration of indium In-111 pentetreotide.
7. Octreotide acetate and the natural somatostatin hormone may be associated with cholelithiasis, presumably by altering fat absorption and possibly by decreasing motility of the gallbladder. A single dose of indium In-111 pentetreotide is not expected to cause cholelithiasis.
8. As with any other radioactive material, appropriate shielding should be used to avoid unnecessary radiation exposure to the patient, occupational workers, and other persons.
9. Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.

##### Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been performed with indium In-111 pentetreotide to evaluate carcinogenic potential or effects on fertility. Pentetreotide was evaluated for mutagenic potential in an in vitro mouse lymphoma forward mutation assay and an in vivo mouse micronucleus assay; evidence of mutagenicity was not found.

##### Pregnancy Category C

Animal reproduction studies have not been conducted with indium In-111 pentetreotide. It is not known whether indium In-111 pentetreotide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, indium In-111 pentetreotide should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus.

##### Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when indium In-111 pentetreotide is administered to a nursing woman.

##### Pediatric Use

Safety and effectiveness in children have not been established.

#### ADVERSE REACTIONS

The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin.

Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetreotide is approximately 5 to 20 times less than for octreotide and is subtherapeutic. The following adverse reactions have been associated with octreotide in 3% to 10% of patients: nausea, injection site pain, diarrhea, abdominal pain/discomfort, loose stools, and vomiting. Hypertension and hyper- and hypoglycemia have also been reported with the use of octreotide.

#### DOSAGE AND ADMINISTRATION

Before administration, a patient should be well hydrated. After administration, the patient must be encouraged to drink fluids liberally. Elimination of extra fluid intake will help reduce the radiation dose by flushing out unbound, labeled pentetreotide by glomerular filtration. It is also recommended that a mild laxative (e.g., bisacodyl or lactulose) be given to the patient starting the evening before the radioactive drug is administered, and continuing

for 48 hours. Ample fluid uptake is necessary during this period as a support both to renal elimination and the bowel-cleansing process. In a patient with an insulinoma, bowel-cleansing should be undertaken only after consultation with an endocrinologist.

The recommended intravenous dose for planar imaging is 111 MBq (3.0 mCi) of indium In-111 pentetreotide prepared from an OctreoScan kit. The recommended intravenous dose for SPECT imaging is 222 MBq (6.0 mCi) of indium In-111 pentetreotide.

The dose should be confirmed by a suitably calibrated radioactivity ionization chamber immediately before administration.

As with all intravenously administered products, OctreoScan should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Preparations containing particulate matter or discoloration should not be administered. They should be disposed of in a safe manner, in compliance with applicable regulations.

Aseptic techniques and effective shielding should be employed in withdrawing doses for administration to patients. Waterproof gloves should be worn during the administration procedure.

Do not administer OctreoScan in TPN solutions or through the same intravenous line.

#### Radiation Dosimetry

The estimated radiation doses\* to the average adult (70 kg) from intravenous administration of 111 MBq (3 mCi) and 222 MBq (6 mCi) are presented below. These estimates were calculated by Oak Ridge Associated Universities using the data published by Krenning, et al.<sup>1</sup>

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium In-111 Pentetreotide\* to a 70 kg patient

	PLANAR		SPECT	
Kidneys	54.16	5.42	108.32	10.83
Liver	12.15	1.22	24.31	2.43
Spleen	73.86	7.39	147.73	14.77
Uterus	6.34	0.63	12.67	1.27
Ovaries	4.89	0.49	9.79	0.98
Testes	2.90	0.29	5.80	0.58
Red Marrow	3.46	0.35	6.91	0.69
Urinary Bladder Wall	30.42	3.04	60.48	6.05
GI Tract				
Stomach Wall	5.87	0.57	11.34	1.13
Small Intestine	4.78	0.48	9.56	0.96
Upper Large Intestine	5.80	0.58	11.59	1.16
Lower Large Intestine	7.73	0.77	15.46	1.55
Adrenals	7.55	0.76	15.11	1.51
Thyroid	7.43	0.74	14.86	1.49
Effective Dose* Equivalent	13.03	1.30	26.06	2.61

1. Values listed include a correction for a maximum of 0.1% indium In-114m radiocontaminant at calibration.

2. E.P. Krenning, W.H. Bakker, P.P.M. Kooij, W.A.P. Breeman, H.Y.Oei, M. de Jong, J.C. Reubi, T.J. Visser, C. Bruns, D.J. Kwekboom, A.E.M. Reits, P.M. van Hagen, J.W. Köper, and S.W.J. Lamberts, "Somatostatin Receptor Scintigraphy with Indium-111-DTPA-D-Phe-1-Octreotide in Man: Metabolism, Dosimetry and Comparison with Iodine-123-Tyr-3-Octreotide," *The Journal of Nuclear Medicine*, Vol. 33, No. 5, May 1992, pp. 652-658.

3. Assumes 4.8 hour voiding interval and International Commission on Radiological Protection (ICRP) 30 model for the gastrointestinal tract calculations.

4. Estimated according to ICRP Publication 53.

#### HOW SUPPLIED

The OctreoScan kit, NDC 0019-9050-40, is supplied with the following components:

1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of:
  - (i) 10 µg pentetreotide [N-(diethylenetriamine-N,N,N',N'-tetraacetic acid-N'-acetyl)-D-phenylalanyl-L-homocystinyl-L-phenylalanyl-L-tryptophyl-L-tyrosyl-L-threonyl-L-homocystinyl-L-threoninyl cyclic (2-7) disulfide], (also known as octreotide DTPA),
  - (ii) 2.0 mg gentamic acid [2,5-dihydroxybenzoic acid],
  - (iii) 4.9 mg triiodine citrate, anhydrous,
  - (iv) 0.37 mg citric acid, anhydrous, and
  - (v) 10.0 mg inositol.

Before lyophilization, sodium hydroxide or hydrochloric acid may have been added for pH adjustment. The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

2. A 10-mL vial of Indium In-111 Chloride Sterile Solution, which contains 1.1 mL of 111 MBq/mL (3.0 mCi/mL) indium In-111 chloride in 0.02 N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 µg/mL (ferric ion, 1.2 µg/mL). The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

In addition, the kit also contains the following items: (1) a 25 G x 5/8" needle (B-D, Monoject) used to transfer Indium In-111 Chloride Sterile Solution to the OctreoScan Reaction Vial, (2) a pressure sensitive label, and (3) a package insert.

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1. Termanini B, Gibril F, Reynolds JC, et al. Value of Somatostatin Receptor Scintigraphy: A Prospective Study in Gastrinoma of its Effect on Clinical Management. *Gastroenterology* 1997;112:335-337.



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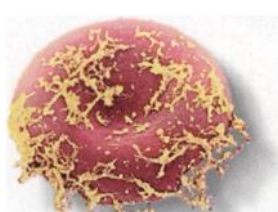
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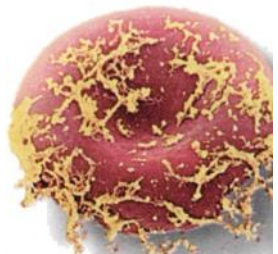
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**Brief Summary**  
**CardioGen-82\***  
**Rubidium Rb 82 Generator**

**For Elution of Rubidium Chloride**  
**Rb 82 Injection**

**Diagnostic: Intravenous**

**INDICATIONS AND USAGE**

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

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

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

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

**CONTRAINDICATIONS**

None known.

**WARNINGS**

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

**PRECAUTIONS**

**General**

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

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

Repeat doses of rubidium chloride Rb 82 injection may lead to an accumulation of the longer lived radioactive contaminants strontium Sr 82 and strontium Sr 85.

Since eluate obtained from the generator is intended for intravenous administration, aseptic techniques must be strictly observed in all handling. Only additive free Sodium Chloride Injection USP should be used to elute the generator. Do not administer eluate from the generator if there is any evidence of foreign matter.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimum radiation exposure to occupational workers.

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

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

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

**Pregnancy Category C**

Animal reproductive studies have not been conducted with rubidium Rb 82. It is also not known whether rubidium Rb 82 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Rubidium Rb 82 should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

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

**Nursing Mothers**

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

**Pediatric Use**

Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS**

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

Issued: March, 1996

(J4-263E)

**References:** 1. Stewart RE, Schwaiger M, Molina E, et al: Comparison of rubidium-82 positron emission tomography and thallium-201 SPECT imaging for detection of coronary artery disease. *Am J Cardiol* 1991;67:1303-1310. 2. Go RT, Marwick TH, MacIntyre WJ, et al: A prospective comparison of rubidium-82 PET and thallium-201 SPECT myocardial perfusion imaging utilizing a single dipyridamole stress in the diagnosis of coronary artery disease. *J Nucl Med* 1990;31:1899-1905.



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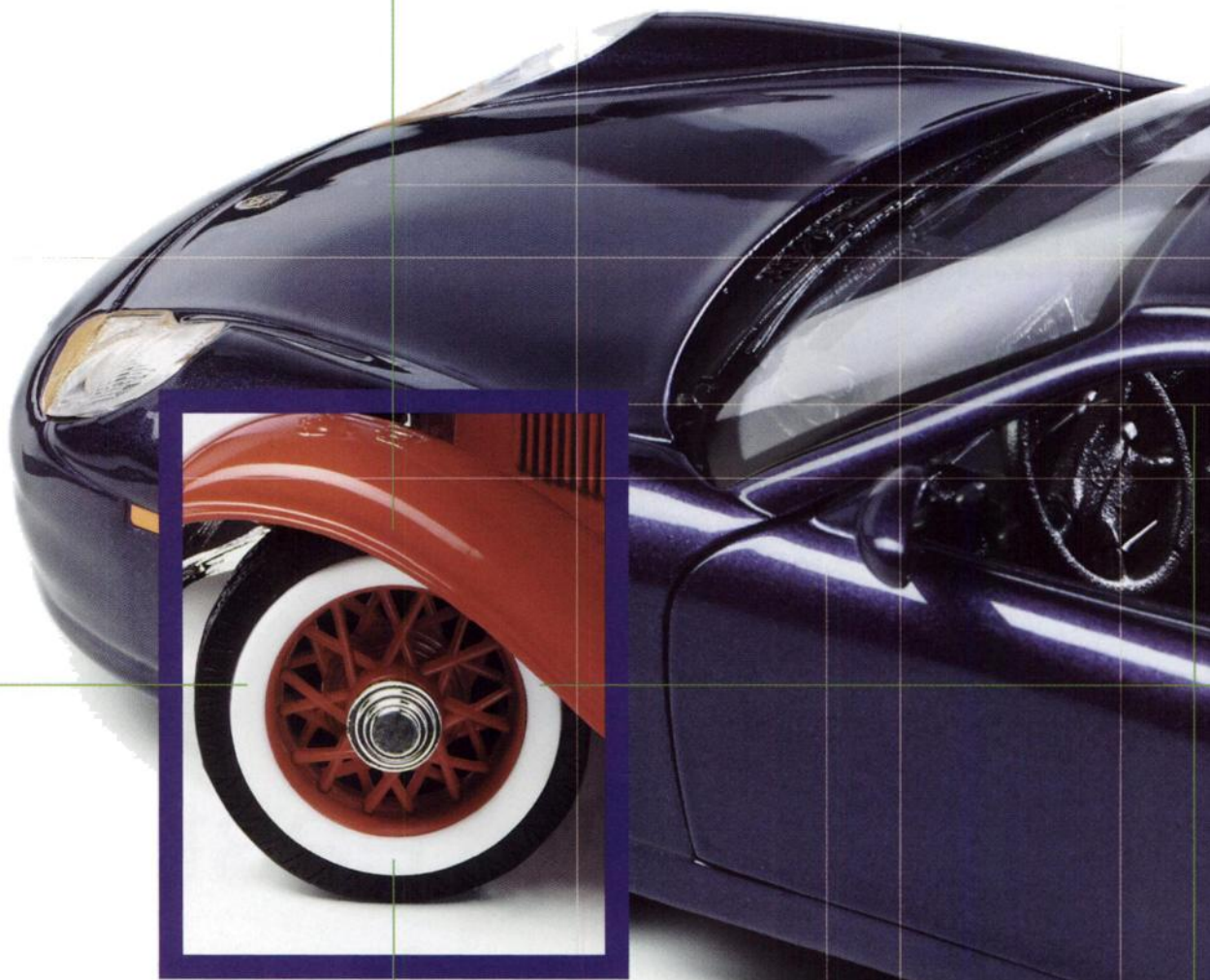
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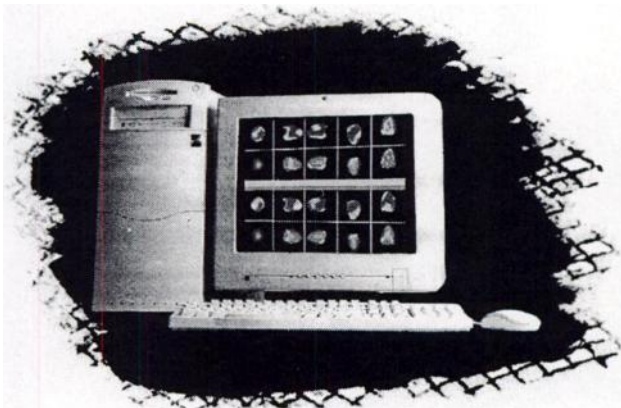
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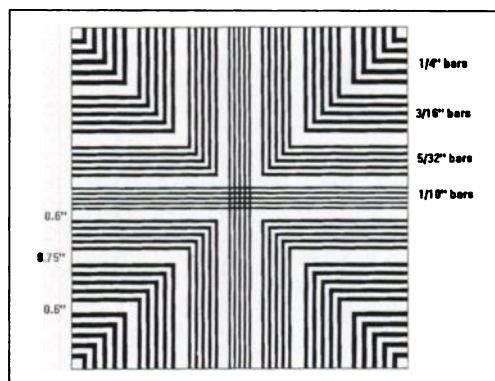
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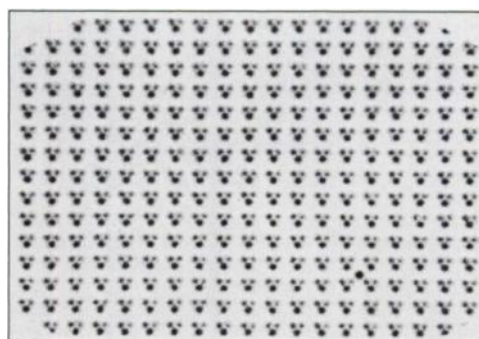
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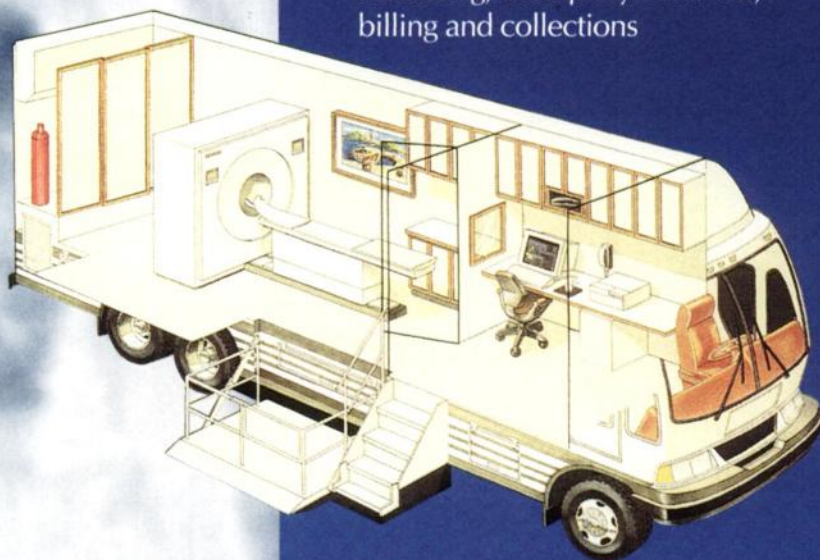
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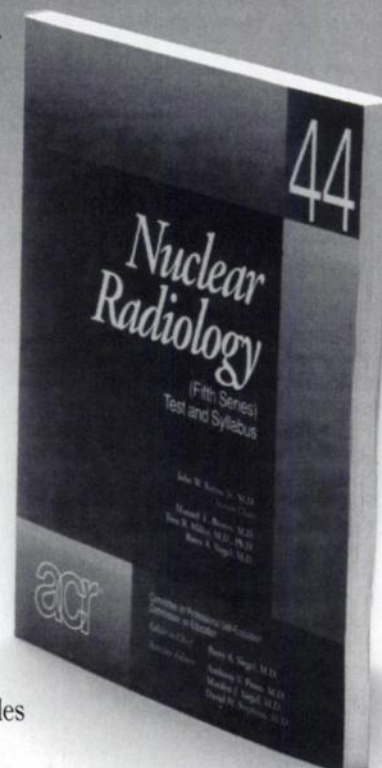
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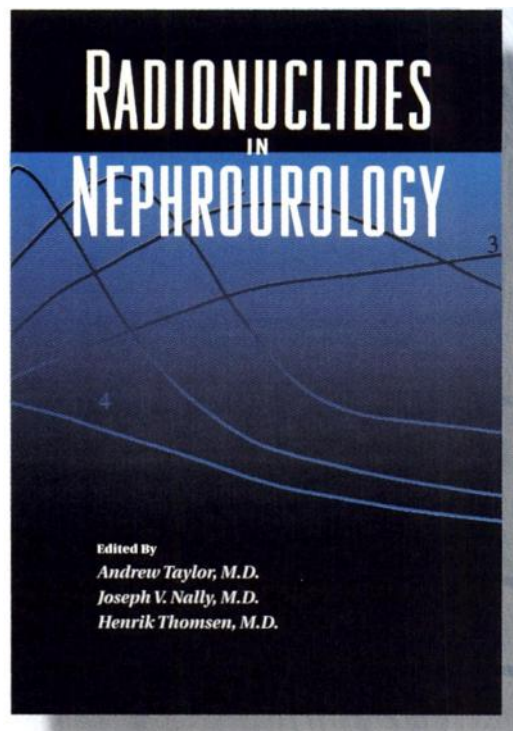
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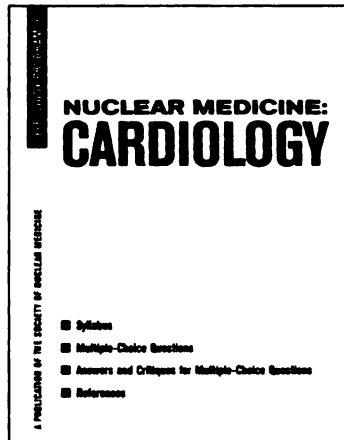
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**Topic 4: Radionuclide Assessment of Congenital Heart Disease (September 1998)**

Contributor: Michael W. Dae, MD

**Note: Topics 3 and 4 appear in one volume.**

**Contributors in remaining Self-Study Cardiology topics include:** Drs. Daniel S. Berman, MD, Cedars-Sinai Medical Center, Los Angeles; Elias Botvinick, MD, University of California, San Francisco; Jamshid Maddahi, MD, UCLA, Los

Angeles; H. William Strauss, Stanford University Medical Center, Stanford; and Mario S. Verani, Methodist Hospital, Houston.

**Topic 5: Myocardial Perfusion Imaging by Single-Photon Radionuclides, part I (February 1998)**

ISBN: 0-932004-57-1

**Topic 6: Myocardial Perfusion Imaging by Single-Photon Radionuclides, part II (Spring 1999)**

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**Topic 7: Imaging Acute Myocardial Infarction (Summer 1999)**

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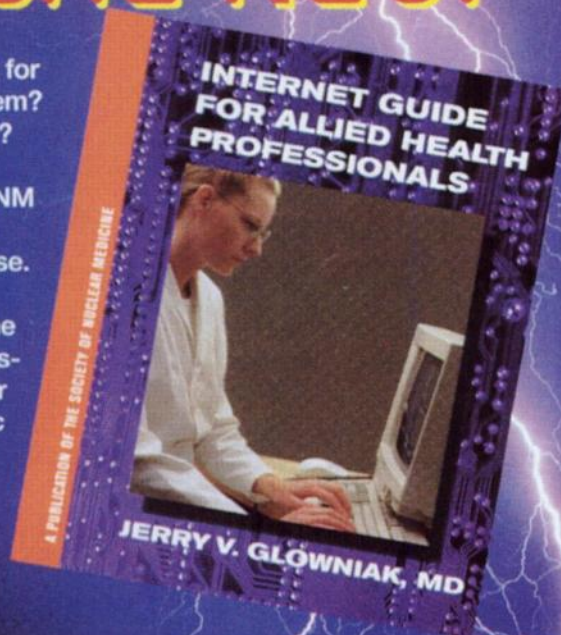
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**BARCELONA** OCTOBER 9-13, 1999

## PROGRAMME OUTLINE

	Saturday 9 October	Sunday 10 October	Monday 11 October	Tuesday 12 October	Wednesday 13 October
08.00-09.30		Continuing Education	Continuing Education	Continuing Education	Continuing Education
09.30-11.00		Plenary Review Lectures	Plenary Review Lectures	Plenary Review Lectures	Submitted Oral Presentations (Parallel Sessions)
11.00-11.30		Break	Break	Break	Break
11.30-13.00		Submitted Oral Presentations (Parallel Sessions)	Submitted Oral Presentations (Parallel Sessions)	Submitted Oral Presentations (Parallel Sessions)	Highlights Lecture
13.00-15.00	Business & Committee Meetings  14.00-17.30	Lunch and Industry Symposia	Lunch and Industry Symposia	Lunch and Industry Symposia	Farewell Cocktail
15.00-16.30		Poster Session	Submitted Oral Presentations (Parallel Sessions)	Submitted Oral Presentations (Parallel Sessions)	
16.30-17.00		Break	Break	Break	
17.00-18.30		Submitted Oral Presentations (Parallel Sessions)	Submitted Oral Presentations (Parallel Sessions)	Members' Assembly	
EVENING	19.00-20.30 Opening Ceremony & 21.00 Welcome Reception		20.00 Concert Palau de la Música	21.00 Mediterranean Dinner	

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June 10  
October 1  
October 9-13

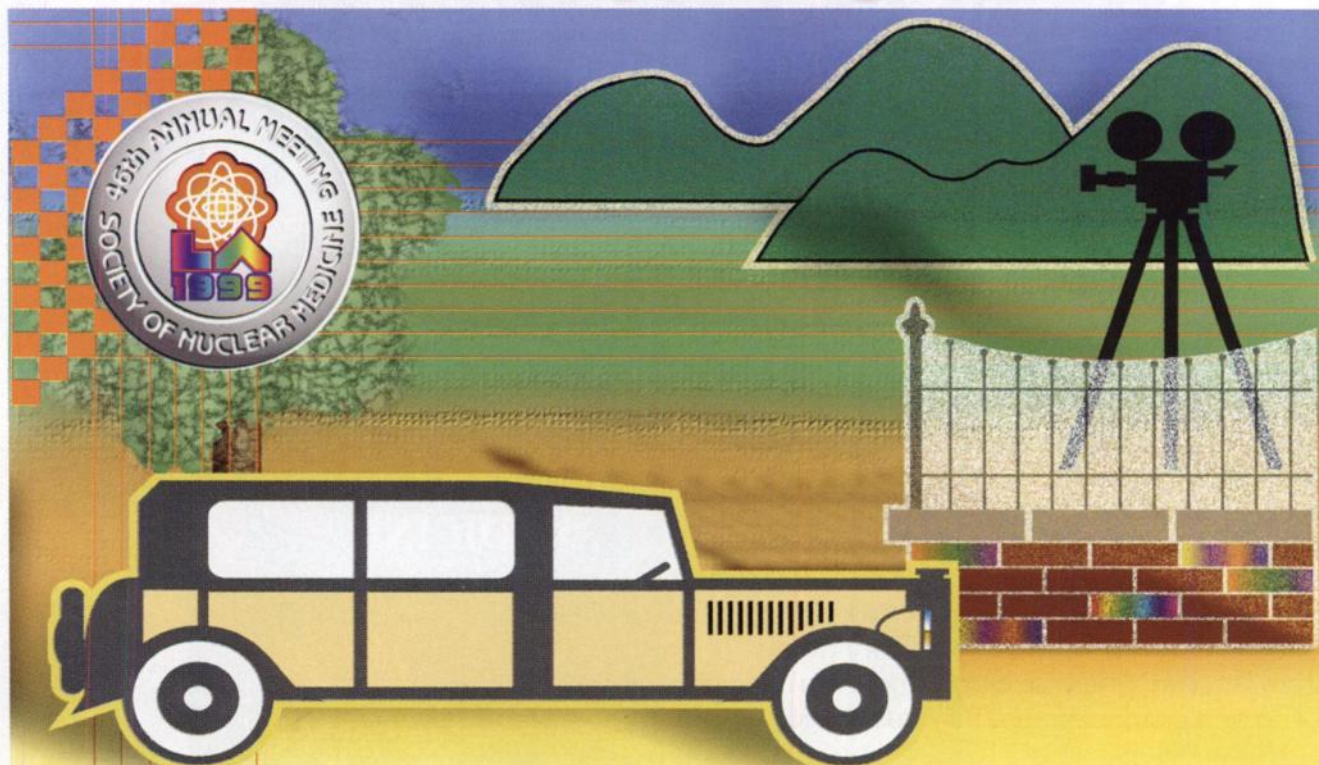
Deadline for submission of abstracts  
Confirmation of accepted abstracts  
End of reduced rate registration  
Beginning of on site registration rate  
European Association of Nuclear Medicine Congress

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The Technologist Section

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*A Publication of the Society of Nuclear Medicine*

# DIAGNOSTIC PATTERNS IN NUCLEAR MEDICINE

**Authors: Edward B. Silberstein, MD  
John G. McAfee, MD  
Andrew P. Spasoff**

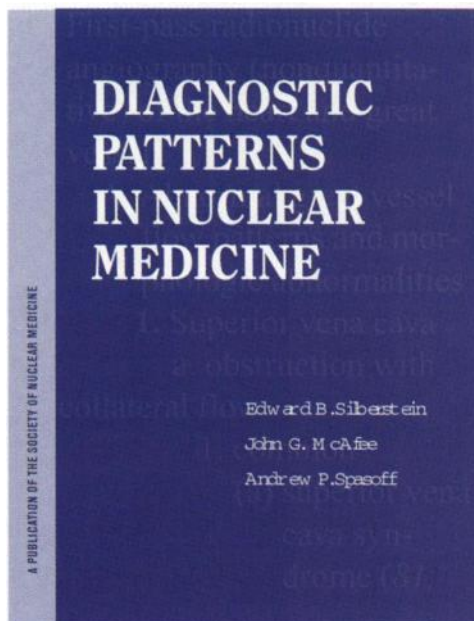
This reference book provides a complete list of differential diagnoses for virtually every pattern described in modern nuclear medicine scintigraphy, including the latest findings in nuclear cardiology, PET, antibody and somatostatin receptor imaging. A full list of all diagnostic patterns reported for every organ system is given. Pharmacologic effects on labeling and distribution are fully described.

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## **Table of Contents**

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- Part II:** Central Nervous System
- Part III:** Endocrine System
- Part IV:** The Eye
- Part V:** Gallium Imaging
- Part VI:** Gastrointestinal System
- Part VII:** Genitourinary System
- Part VIII:** Hematologic Studies/Diseases
- Part IX:** Peri-Diaphragmatic Disease
- Part X:** Pulmonary System
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The website's data entry form will collect information from nuclear medicine practitioners to compile a utilization analysis database.

The database contains information on:

- Facility type and location
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- Inpatient and outpatient procedures for a selected set of commonly used nuclear medicine CPT-4 codes

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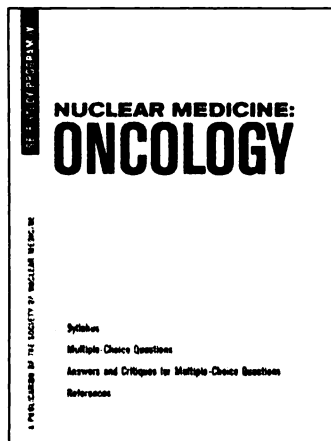
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For more information or to participate in this program, contact Katrina Young, UA Project Coordinator, at (703) 708-9000 x255 or e-mail: [kyoung@snm.org](mailto:kyoung@snm.org).



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**Series Editor:** Thomas P. Haynie, MD

**Oncology Series Writers:** Gerald L. Denardo, MD, Randall Hawkins, MD, PhD, E. Edmund Kim, MD, Alexander J. McEwan, MD, Hani A. Nabi, MD, Patrice K. Rehm, MD, Edward B. Silberstein, MD and Richard Wahl, MD

**Published**

**Topic Booklet 1: Oncology Overview (July 1997)**

ISBN 0-932004-51-2

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**Published**

**Topic Booklet 2: Conventional Tumor Imaging (October 1999)**

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| 02 <input type="checkbox"/> Diagnostic radiology    | 11 <input type="checkbox"/> Nuclear radiology         |
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## Nuclear Medicine Physician—University of Southern California, School of Medicine, Department of Radiology

The Department of Radiology at the University of Southern California has an immediate opening for a Nuclear Medicine Physician to join the Radiology staff, with responsibilities for clinical, teaching and research. Qualified candidate will have successfully completed board certification in Nuclear Medicine in an ACGME accredited program or ABR certified with CAQ in Nuclear Radiology. Must have a California License.

Position will be Assistant or Associate Professor on a clinical or tenure track depending on qualifications. Located on the USC/LA County Health Science Campus, which encompasses a large public hospital, a tertiary care university teaching hospital, an NCI supported cancer center, outpatient imaging facilities and PET center. Performing 13,000 procedures per year, the facilities encompasses 13 state-of-the-art gamma cameras and a dedicated PET scanner.

USC offers competitive salary and excellent fringe benefits. EOE. Qualified applicants should send CV, 3 letters of recommendations, a personal statement of interest and current certificates to Peter S. Conti, MD, PhD, PET ISC, 1510 San Pablo St., Suite 350, Los Angeles, CA 90033 or fax to (323) 442-5778.



**Nuclear Medicine  
Portland, Oregon**

Northwest Permanente, P.C., a physician-managed multi-specialty group serving over 440,000 members of Kaiser Permanente in the Northwest has an excellent opportunity for a physician (board certified or eligible) in Nuclear Medicine in the Portland area. The position is half-time Nuclear Medicine with additional time available in radiology.

Our program in Oregon and Washington offers a collegial and professionally stimulating environment in one of the most successful managed care systems in the country, plus a quality lifestyle in the Pacific Northwest. In addition we provide a competitive salary and benefits package which includes a generous retirement program, sabbatical leave, professional liability coverage and more. Please forward CV to:

N.M. Clark, Director, Professional Resources, Northwest Permanente, P.C., 500 NE Multnomah, Suite 100, Portland, OR 97232-2099. EOE.

### **Nuclear Medicine Fellowship Position University of Alabama at Birmingham**

A one or two year fellowship position in Nuclear Medicine imaging is available beginning July 1, 1999 in the Division of Nuclear Medicine, Department of Radiology, at the University of Alabama at Birmingham Medical Center. The Imaging Fellowship will emphasize brain SPECT imaging but will also include PET imaging and other Nuclear Medicine clinical research projects. Applicants should have at least one year of experience in Nuclear Medicine or Radiology, have an intense interest in imaging research, and be eligible for licensure in the state of Alabama. Successful candidates will assume a significant role on multiple research projects involving all aspects of clinical brain SPECT imaging, triple head dynamic brain SPECT, quantitative Xe-133 brain SPECT on the Picker Prism, F-18 FDG PET imaging using the ADAC MCD coincidence camera and conventional PET, 4.1T NMR spectroscopic imaging, and 4.1T functional MRI (fMRI). Please send letter of interest and curriculum vitae to: James M. Mountz, MD, PhD, Director of Neuro-Nuclear Imaging, Division of Nuclear Medicine, Department of Radiology, The University of Alabama at Birmingham, 619 South 19th Street, Birmingham, AL 35233-6835. Phone: (205) 975-8336. Fax: (205) 934-5589. E-mail: jmmountz@uab.edu. UAB is an Affirmative Action/Equal Opportunity Employer.

## **NUCLEAR MEDICINE TECHNOLOGIST**



The Johns Hopkins Hospital, ranked "Best of the Best" by *U.S. News and World Report* for eight consecutive years, is seeking a certified Nuclear Medicine Technologist to work in the Department of Radiology. While reporting to the Chief Technologist, you will be responsible for performing or assisting in the performance of diagnostic exams including preparation and administration of radio pharmaceuticals, radio nuclide imaging and dynamic studies.

Your excellent interpersonal skills will be needed to provide physicians with reports and results and interact with all levels of staff, patients, visitors and other hospital employees. Successful completion of an approved curriculum in Nuclear Medicine Technology and Maryland state licensure are required.

Johns Hopkins will reward you with competitive compensation, excellent benefits including 100% tuition reimbursement and an environment in which you can rise to levels of increasing responsibility. For consideration, please forward your resume to: The Johns Hopkins Hospital, Office of Career Services, 600 North Wolfe Street, Houck 3rd Floor, Baltimore, MD 21287-1454; Fax: (410) 614-2960. EOE/AA, m/f/d/v.



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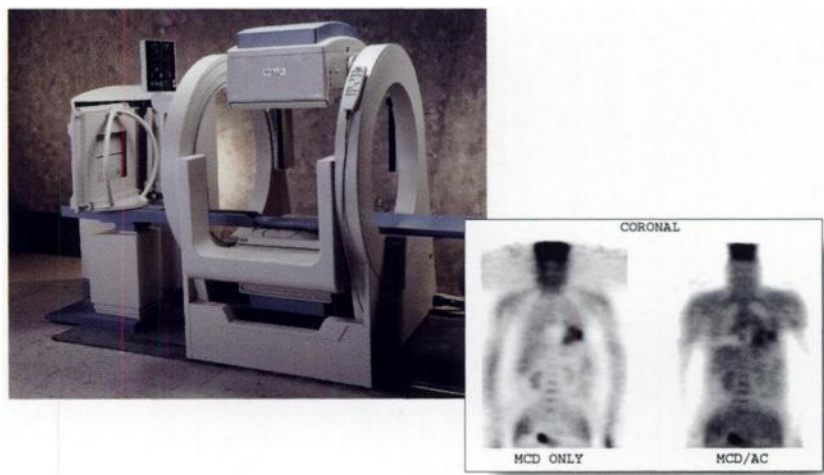


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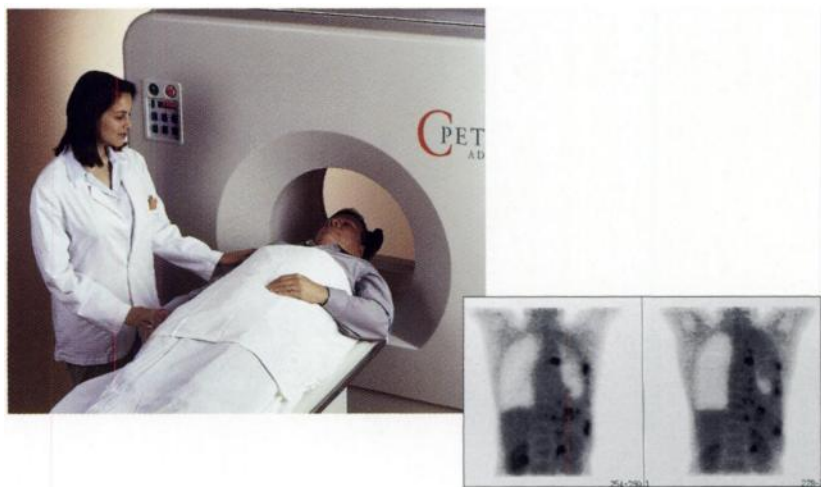
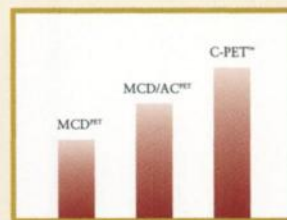


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