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

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- Profile non-uniform attenuation correction
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- Emory cardiac quantitative 'toolbox'
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  - Wall motion analysis
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Medical Imaging
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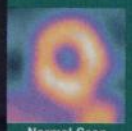
When the stress EKG is nondiagnostic in women or other challenging patients...

# "Now what?"

## Order Cardiolite® to minimize false-positives;[1,2] 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*[3,4] 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[1,2] and in other patients who are challenging to image.*[5,6] 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[1,2]—minimizing false-positives or equivocal results by clearly distinguishing breast attenuation from true cardiac defects.[1,2]

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[7,8]—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.

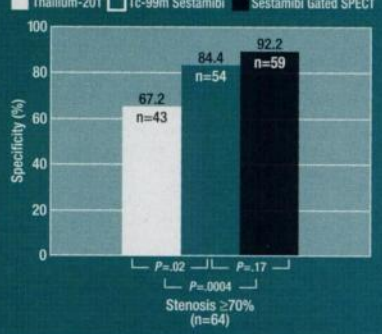
**For more information contact us at 1-800-343-7851 or www.cardiolite.com**

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

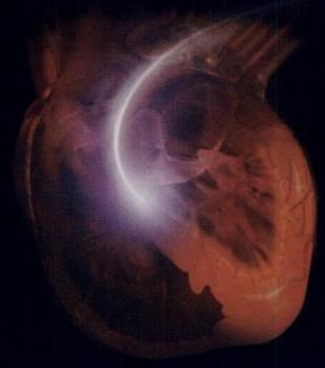
*This includes patients with large, dense breasts; COPD; narrow intercostal space; or mixed ischemia and scar; as well as those who are obese, are unable to exercise, or have nondiagnostic EKGs.
Please see brief summary of prescribing information on the following page.

**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 Echocard.* 1995;8:S23. **7.** Travin MI et al. *Am Heart J.* 1997;134:73-82. **8.** Hachamovitch R et al. *J Am Coll Cardiol.* 1996;28:34-44.

**Increase Specificity† With Gated SPECT Using Cardiolite®†**




† 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.[1]



# Cardiolite®

Kit for the Preparation of Technetium Tc99m Sestamibi for Injection

**It clears your line of vision**

**Brief Summary**

# Cardiolite®

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

**INDICATIONS AND USAGE:** Myocardial Imaging: CARDIOLITE®, 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® 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™, 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™ 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® imaging. Patients who receive CARDIOLITE® or MIRALUMA™ 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® or MIRALUMA™, 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® and MIRALUMA™ 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, $[Cu(MIBI)_4]BF_4$, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all in vitro). At cytotoxic concentrations (≥ 20 µg/mL), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. $[Cu(MIBI)_4]BF_4$ did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg, > 600 X maximal human dose).

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

**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 ≤ 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, asthenia, 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® 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™ 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 isolateral arm comfortably above the head, shoulders flat against the table, head turned to the side and relaxed, with the breast imaged pendent 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

REST

| | 2.0 hour void | | 4.8 hour void | |
|---|---|---|---|---|
| Organ | 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 |

STRESS

| | 2.0 hour void | | 4.8 hour void | |
|---|---|---|---|---|
| Organ | 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®, 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 105 CMR 120.500 for the uses listed in 105 CMR 120.533 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, Agreement States or Licensing States.

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# Capintec has created the perfect match.

# Just what you've been looking for.

Capintec's new CRC-15W is a combination of the popular CRC-15R dose calibrator and the CAPRAC-R Well Counter. The CRC-15W allows nuclear medicine departments the ability to perform dose measurements, wipe tests, and lab tests all in one unit.

The dose calibrator chamber provides advanced microprocessor features with the speed and accuracy you need to measure activity and prepare doses. The CRC-15W also performs counting functions for lab and wipe tests in as little as 6 seconds at activities as low as 1 nCi. For wipe testing, the CRC-15W allows the user to define specific counting procedures (protocols) with trigger levels for work, patient, unrestricted areas and sealed source leak tests. The chamber and counter of the CRC-15W are combined in a menu-driven, push button interface that is easy to learn and use.

The CRC-15W is simply another example of how Capintec can be relied upon for excellence in energy measurement for all nuclear medicine department needs.

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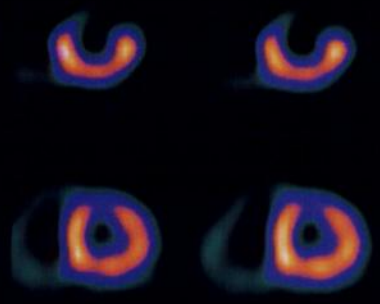
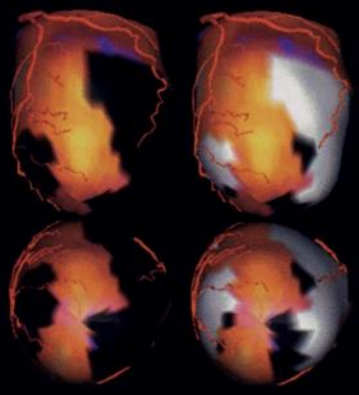
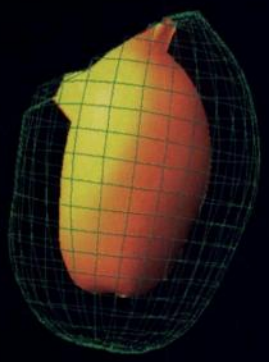


Profile Attenuation Correction



Emory Cardiac Toolbox



Cedars Gated SPECT Quantification

# ology

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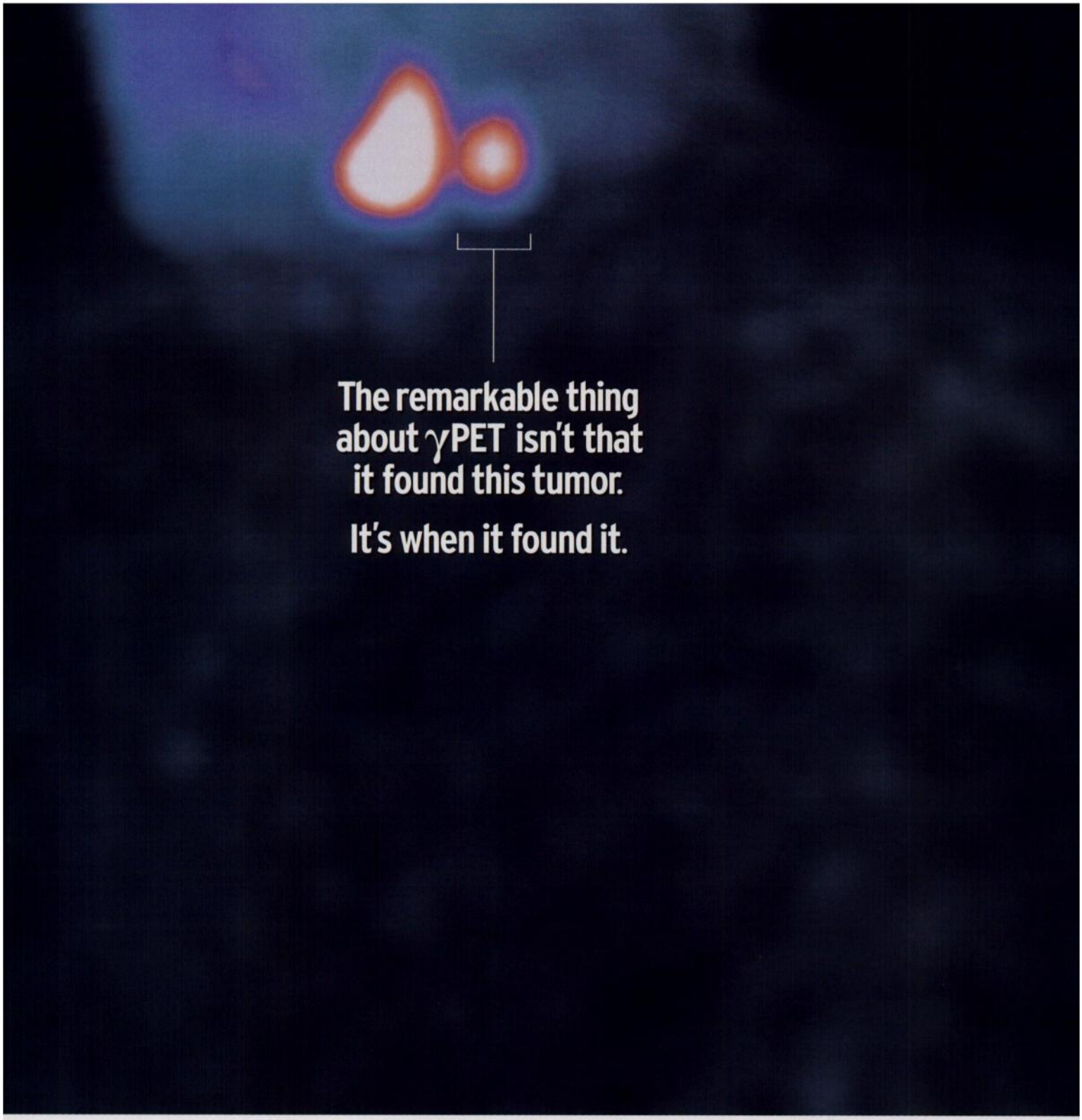
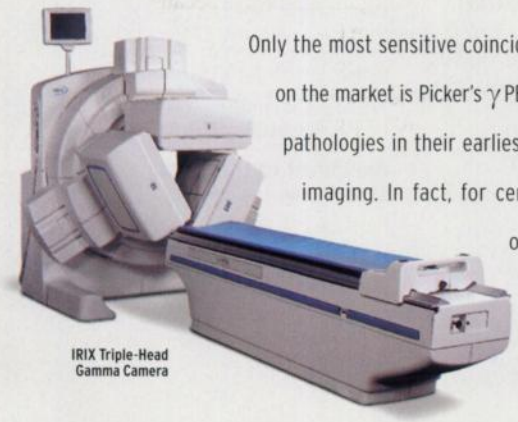


# The remarkable thing about γPET isn't that it found this tumor.

# It's when it found it.



IRIX Triple-Head Gamma Camera

Only the most sensitive coincidence imaging technology can detect a tumor this small. And the most sensitive coincidence imaging package on the market is Picker's γPET³.* Available on the IRIX™ the industry's only triple-head, variable-angle gamma camera, γPET³ can help you detect pathologies in their earliest, most treatable stages. And IRIX delivers outstanding image quality, whether you're performing PET or SPECT imaging. In fact, for certain clinical applications, its detection capabilities are comparable to even a dedicated PET system. All of which means γPET³ gives you something even more remarkable than a clear image of the pathology. It gives you the time to treat it.

For more information, contact us at 440-473-3000 or www.picker.com.

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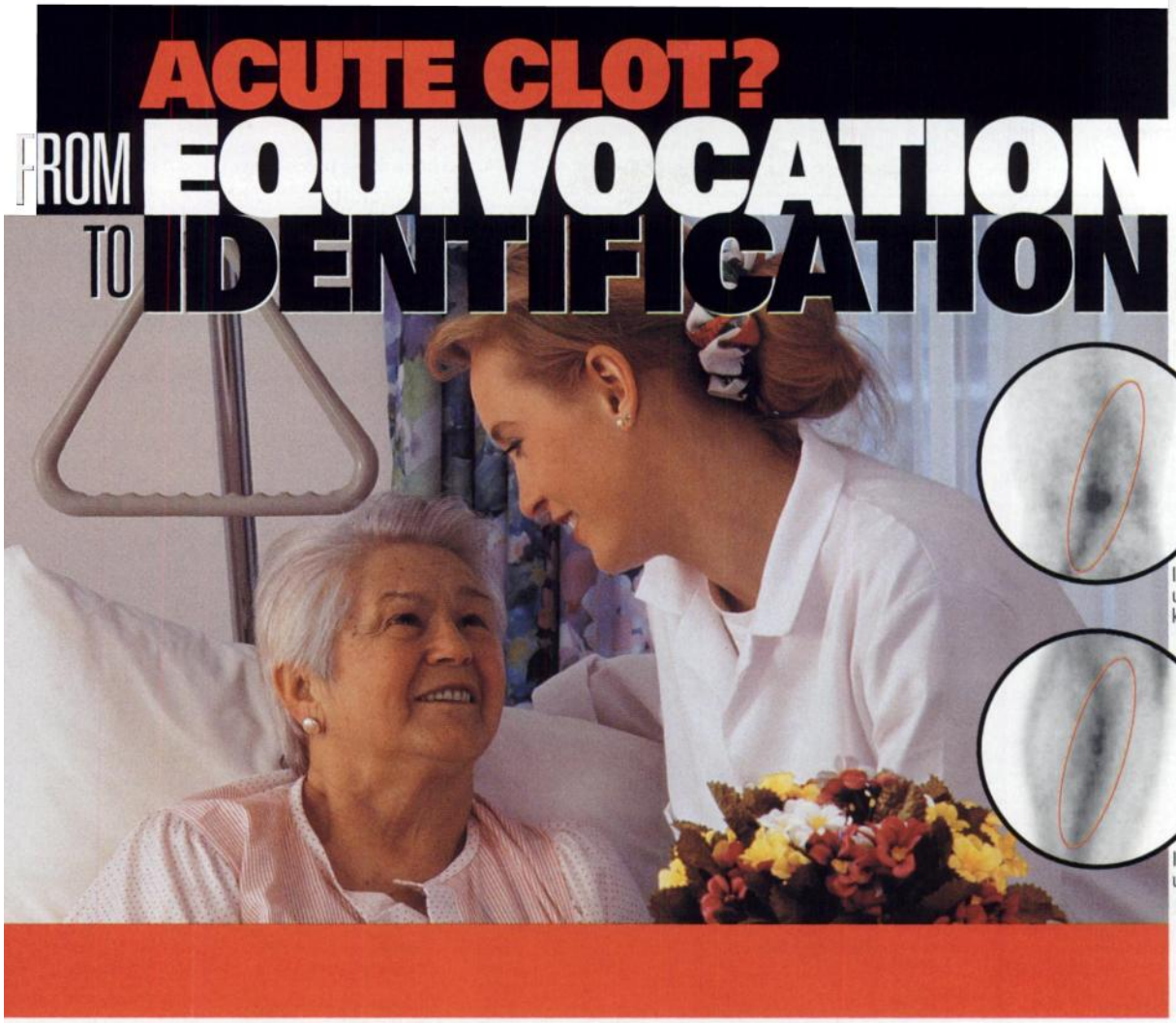
*Works in progress

# ACUTE CLOT?

# FROM EQUIVOCATION TO IDENTIFICATION




# ACUTECT™

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

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

AcuTect—a unique, radiolabeled synthetic peptide[1]—is the first to offer you the ability to clearly, safely, and comfortably target *acute* clots. AcuTect is indicated for scintigraphic imaging of acute venous thrombosis in the lower extremities of patients who have signs and symptoms of acute venous thrombosis.[1] AcuTect binds preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets.[1,2] AcuTect appears to detect acute and not chronic venous thrombosis. This is based on in vivo and ex vivo animal data; not confirmed clinically.[1] The result is a new sensitivity that challenges venography—the "gold standard."

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

---

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

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

**For customer service, call 1-877-DIATIDE.**

## The difference is acute.

---

Diatide, Inc.

WE'VE GOT YOUR SOLUTIONS. Nycomed Amersham

Please see brief summary of prescribing information on following page.

# ACUTECT™

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

### BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please consult Full Product Information before using.

### DESCRIPTION

AcuTect™, Kit for the Preparation of Technetium Tc 99m Apcitide Injection, is intended for use in the preparation of technetium Tc 99m apcitide, a diagnostic radiopharmaceutical to be used by intravenous injection. Each vial contains a sterile, nonpyrogenic lyophilized mixture which is formulated with 100 µg of bibapcitide, 75 mg of sodium glucoheptonate dihydrate, 89 µg of stannous chloride dihydrate, and sufficient sodium hydroxide or hydrochloric acid to adjust the pH to 7.4 prior to lyophilization. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product does not contain an antimicrobial preservative.

Bibapcitide is composed of two apcitide monomers. When sterile, nonpyrogenic Sodium Pertechnetate Tc 99m Injection in 0.9% Sodium Chloride Injection, U.S.P., is added to the vial and heated, the bibapcitide is split and forms a technetium-99m complex of apcitide.

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

**CONTRAINDICATIONS:** None known.

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

After administration of AcuTect™, as with the administration of other intravenous drugs, patients with a history of drug reactions, other allergies, or immune system disorders should be observed for several hours. A fully equipped emergency cart, or equivalent supplies and equipment, and personnel competent in recognizing and treating anaphylactic reactions should be available. (See Adverse Reactions Section.)

### PRECAUTIONS

***General***

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

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

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

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

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

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

***Information for Patients***

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

***Laboratory Tests***

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

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

***Drug Interactions***

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

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

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

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

***Pregnancy***

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

***Nursing Mothers***

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

***Pediatric Use***

Safety and effectiveness in pediatric patients have not been established.

### ADVERSE REACTIONS

Adverse events were evaluated in clinical studies of 642 adults who received technetium Tc 99m 20.0 mCi labeled to approximately 70-100 µg of bibapcitide. Of these adults, 46% were women and 54% men. The mean age was 57.0 years (17 to 95 years). In all patients, adverse events were monitored for at least 3 hours. In a subset of 169 patients, adverse events were monitored for 24 hours. Deaths did not occur during the clinical study period. Following injection of technetium Tc 99m apcitide, a serious episode of hypotension occurred in one patient who had acute hypotension that began within 10 minutes of injection and, over 60 minutes, progressed to a systolic pressure of 70 mm Hg.

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

**Table 1: ADVERSE EVENTS REPORTED IN ≥0.5 % OF PATIENTS FOLLOWING AcuTect™ INJECTION IN CLINICAL STUDIES**

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

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

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

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

Technetium Tc 99m apcitide should be drawn into the syringe and administered using sterile technique. If nondisposable equipment is used, scrupulous care should be taken to prevent residual contamination with traces of cleansing agents. Unused portions of the drug must be discarded appropriately. (See Instructions for Preparation Section of Full Product Information.)

***Lower Extremity Imaging***

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

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

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

### RADIATION DOSIMETRY

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

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

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

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1 rev., Soc. Nucl. Med., 1976). Effective dose equivalent was calculated in accordance with ICRP 53 (Ann. ICRP 18, 1-4, 1988) and gave a value of 0.0093mSv/MBq (0.0034 rem/mCi).

### HOW SUPPLIED

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

***Storage***

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

The kit should be protected from light.

*Rx only*

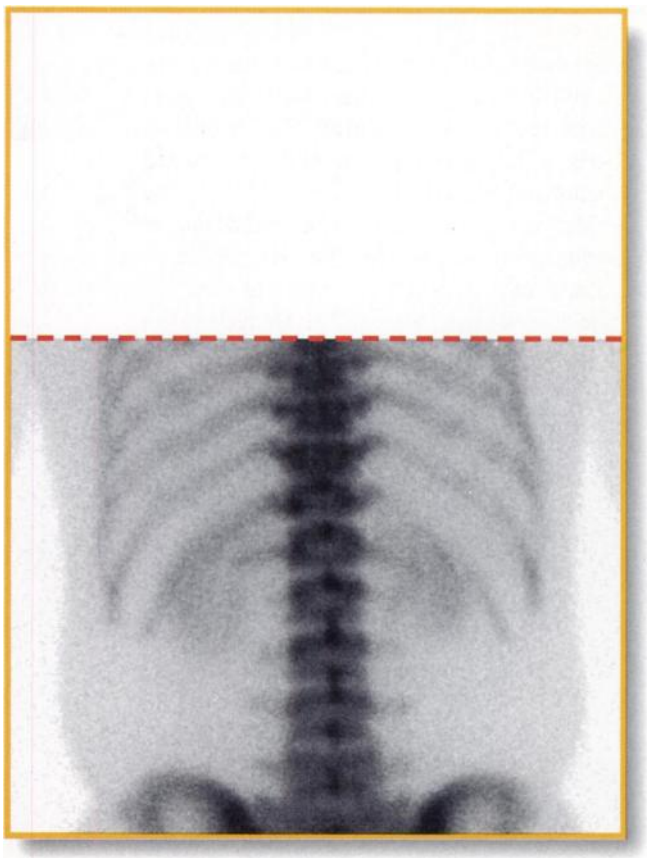
Diatide, Inc.
9 Delta Drive, Londonderry, New Hampshire 03053

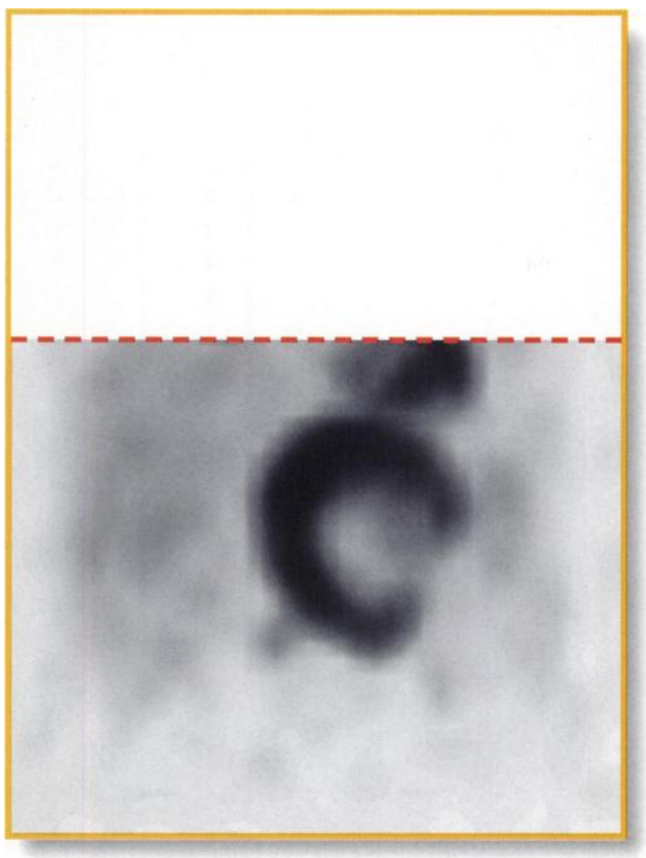
Rev. September 1998
Distributed by: Diatide, Inc. and Nycomed Amersham
60-4500010403



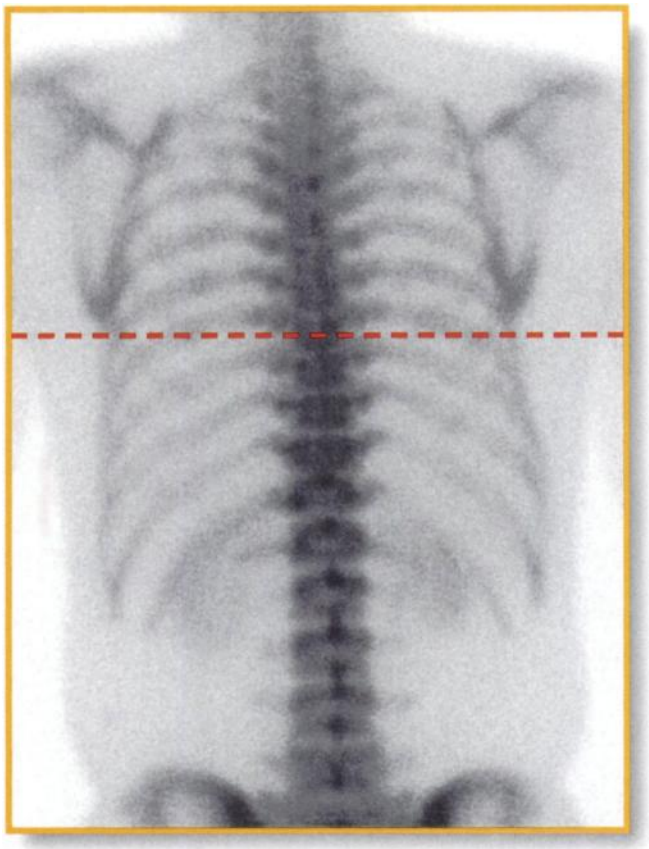
**References: 1.** AcuTect™ Prescribing Information. **2.** Becker RC. Antiplatelet therapy. *Science & Medicine.* July/August 1996:12-21.

# See what you are Missing

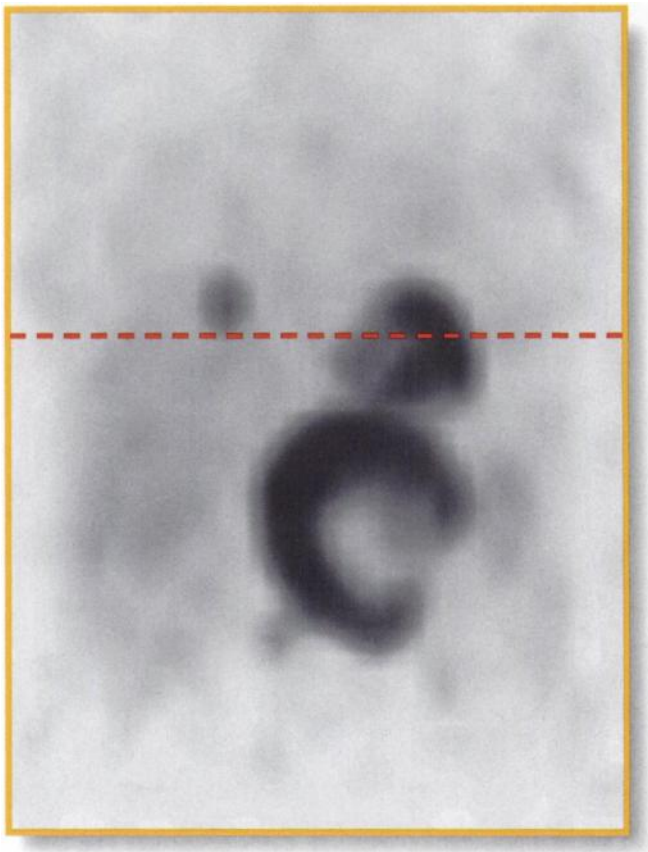




# 40% more coverage in 50% less time with the DST-XLi



*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.***

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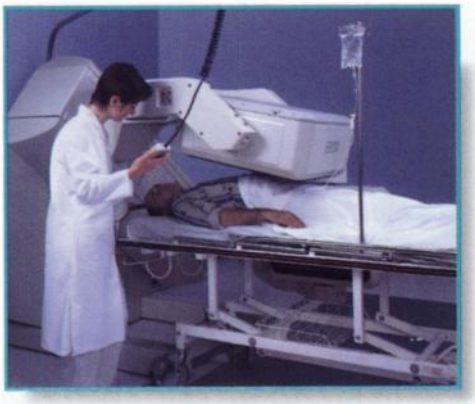
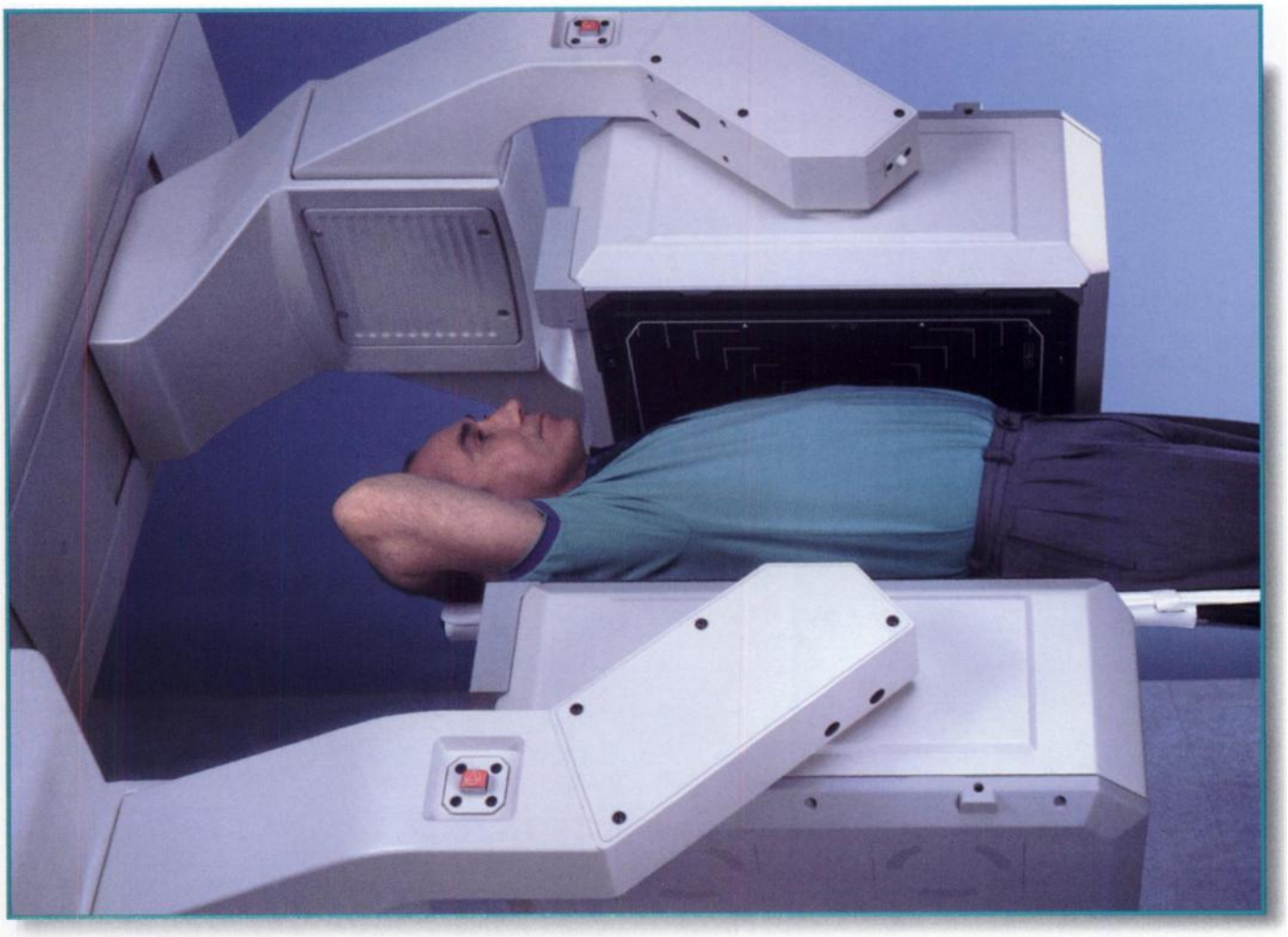
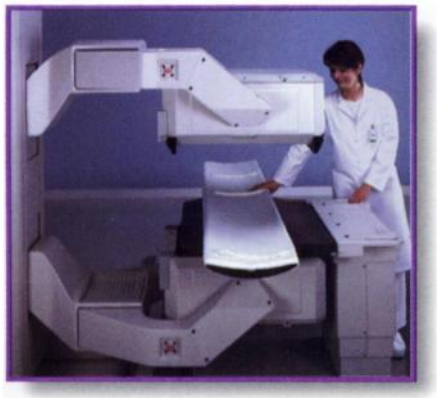


What's more, the DST-XLi delivers its **increased coverage in 50% less time.** Instead of requiring two complete scans to cover the entire torso - as with conventional short axis detector cameras - the DST-XLi does it in one. Think of the efficiency this will give your department. Not to mention the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



# 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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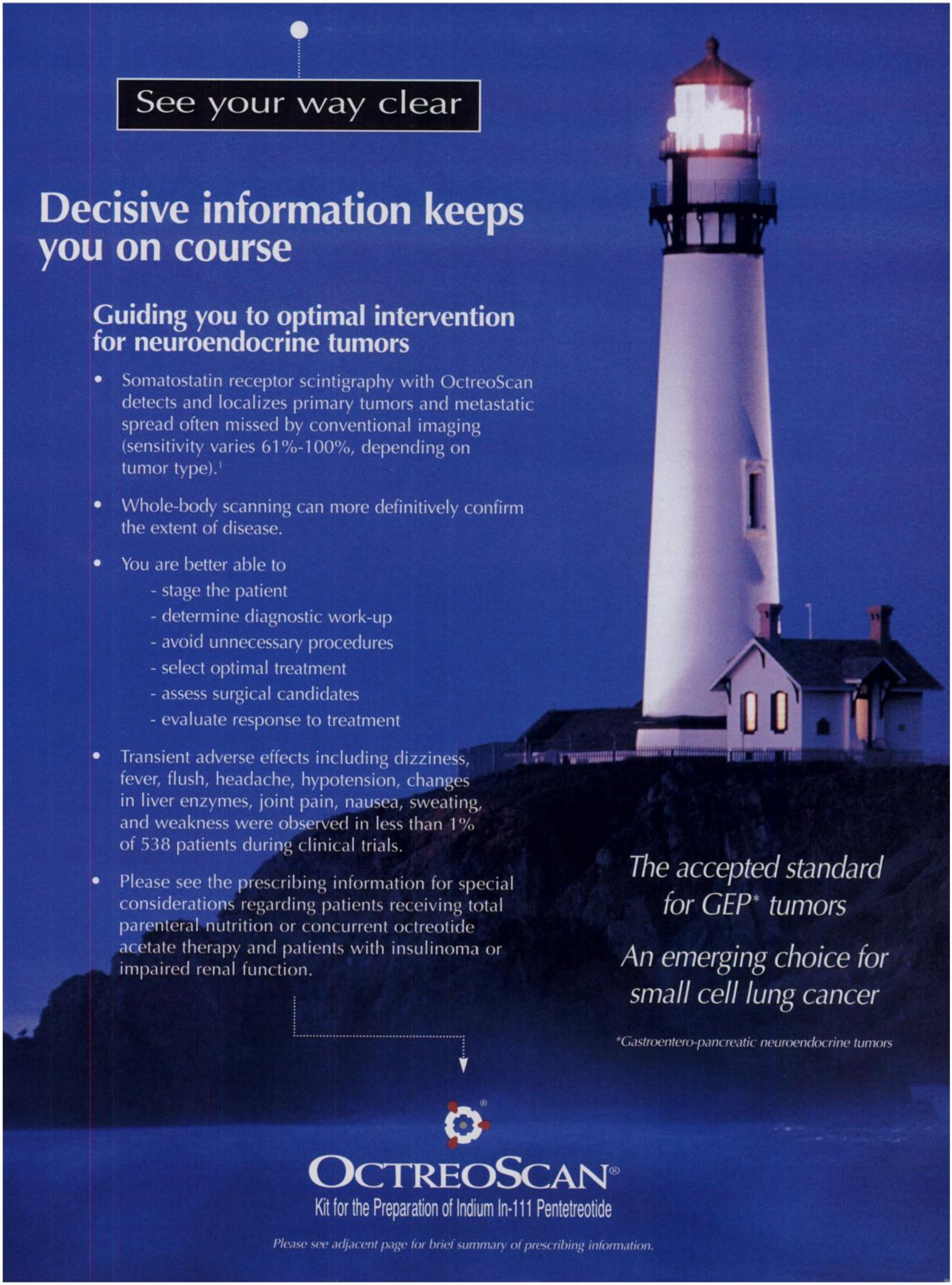
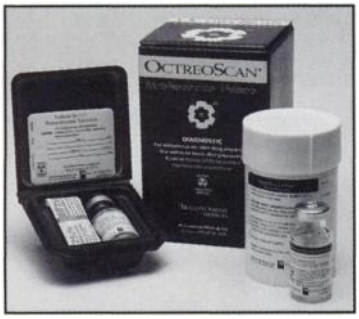

See your way clear
Decisive information keeps you on course
Guiding you to optimal intervention for neuroendocrine tumors
• Somatostatin receptor scintigraphy with OctreoScan detects and localizes primary tumors and metastatic spread often missed by conventional imaging (sensitivity varies 61%-100%, depending on tumor type).[1]
• 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
Please see adjacent page for brief summary of prescribing information.

# OCTREOSCAN®

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

## BRIEF SUMMARY OF PRESCRIBING INFORMATION




DESCRIPTION

OctreoScan® is a kit for the preparation of indium In-111 pentetreotide, a diagnostic radiopharmaceutical. 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, labelled 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[1] 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.[2]

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium In-111 Pentetreotide[3] 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 | 5.67 | 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[4] 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. Kwekkeboom, A.E.M. Reijs, P.M. van Hagen, J.W. Koper, 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-hemicystyl-L-phenylalanyl-D-tryptophyl-L-lysyl-L-threonyl-L-hemicystyl-L-threoninol cyclic (2-7) disulfide], (also known as octreotide DTPA),
   (ii) 2.0 mg gentisic acid [2,5-dihydroxybenzoic acid],
   (iii) 4.9 mg trisodium 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.

MALLINCKRODT

**Mallinckrodt Inc.,**
Mallinckrodt Nuclear Medicine Division
P.O. Box 5840
St. Louis, MO 63134

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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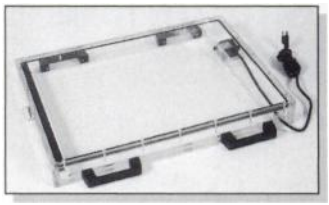

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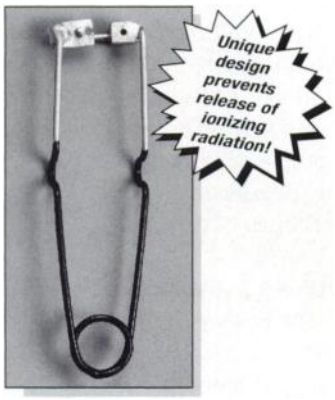


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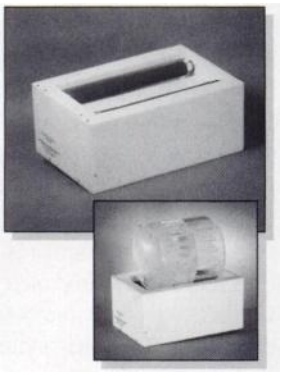

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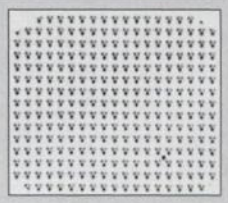

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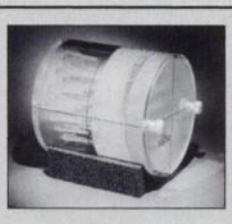

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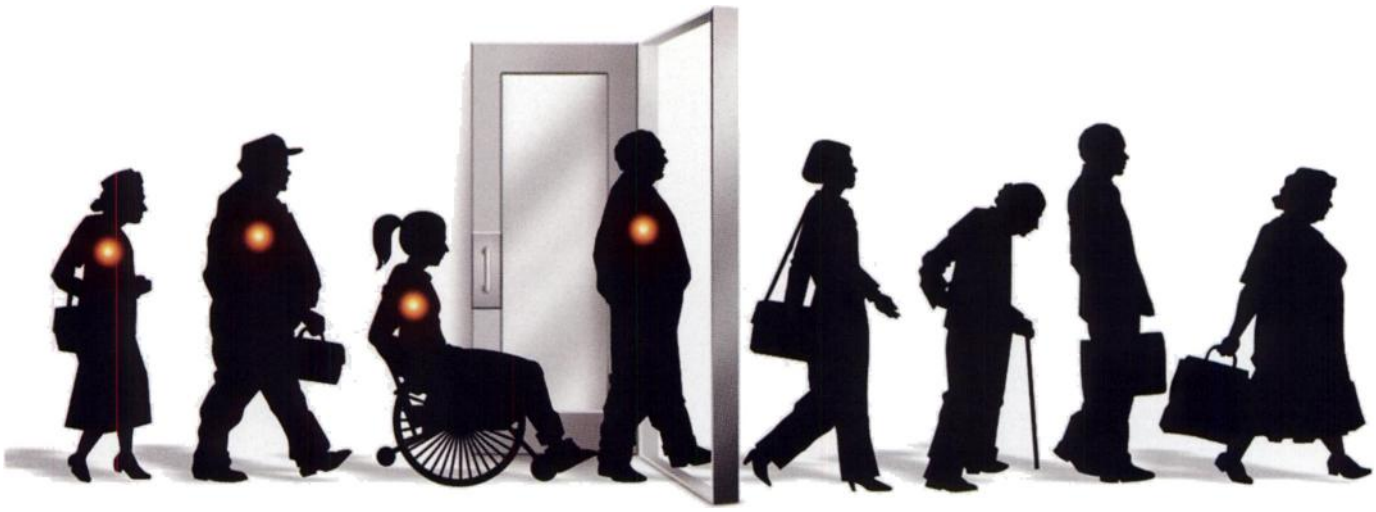

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Give your nuclear department "rapid clearance" capability with MYOVIEW. MYOVIEW clears quickly from the blood, liver, and lungs[1-3] for quality target-to-background ratios and timely imaging (as soon as 15 minutes or up to 4 hours post-injection).[1] 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.

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.



**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 FW, 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™

BS-43-1011A

**Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection**
**Diagnostic Radiopharmaceutical for Intravenous use only**

## Rx ONLY

**Please consult full prescribing information before using. A summary follows:**

## 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-dioxa-6,9-diphosphatetradecane], 30 µg stannous chloride dihydrate (minimum stannous tin 5.0 µg; maximum total stannous and stannic tin 15.8 µg), 0.32 mg disodium sulphosalicylate and 1.0 mg sodium D-gluconate, and 1.8 mg sodium hydrogen carbonate. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

## 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 the following table. The values are listed in descending order as rad/mCi and µGy/MBq and assume urinary bladder emptying at 3.5 hours.

**Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)**

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

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No.1 (rev).Society of Nuclear Medicine, 1976). Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4),1988) and gave values of 8.61 x $10^{-3}$ mSV/MBq and 1.12 x $10^{-2}$ mSV/MBq after exercise and rest, respectively.

**Manufactured by:**
Nycomed Amersham plc
Amersham United Kingdom

Patent No. 5,045,302 (r)

**Distributed by:**
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Revised December 1998





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# Reach for the Stars

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Public Relations STARS

Show pride in your profession by entering the 1999 PR Stars Contest co-sponsored by the Society of Nuclear Medicine-Technologist Section (SNM-TS) and Capintec, Inc.

Your dedication and efforts to the field of nuclear medicine can now be rewarded. Share your promotional activities and efforts completed during 1999 and enter to win recognition and prizes.

**Who is eligible to enter?**
All entrants must be a nuclear medicine technologist and a staff member of a hospital or nuclear medicine facility.

**What do I need to do?**
In short, you need to be creative and persuasive. Describe and document your promotional activities and results throughout the year or for a particular event. Compose a detailed description, including the goals and objectives of your nuclear medicine public relations and promotional activities. More importantly, reinforce nuclear medicine to referring physicians, promote nuclear medicine to healthcare workers, increase community awareness and encourage career paths. Utilize available resources to your advantage and effectively use them to promote and explain the benefits of nuclear medicine to patients and referring physicians.

**What are the prizes?**
Prizes include up to $800 for individual contest entrants and up to $600 for your hospital or institution, up to $650 in airfare to the 47th SNM Annual Meeting in St. Louis, MO, payment of your registration fee to attend the meeting and your SNM-TS membership dues paid for one year. Ten prizes will be awarded.

**Deadline:** December 1, 1999

See the back of this ad for entry form and mailing information.

**Proudly sponsored by**

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# Contest

This is the official entry form for the 1999 PR Stars Contest co-sponsored by the **SNM-TS and Capintec, Inc.** Please **fill out the** entry form and complete **the requested** information. Based **on the information you** provide, a panel of judges **will evaluate the** entries using the point **system outlined** below to select 10 winners.

**Eligibility:**

- All entrants **must be a** nuclear medicine technologist
- All entrants must be a staff member **of** a hospital or nuclear medicine facility
- All entries must be postmarked by December 1, 1999
- All of the following questions must **be** answered in full

**Prizes:**

1st Place: $800 for the individual and **$600** for the institution. Up to $650 in airfare **to** the 2000 SNM Annual Meeting in St. Louis, MO to receive your prize. Payment of your registration fee to attend the 2000 SNM Annual Meeting. Your SNM-TS membership dues paid for one year. Airfare and registration contingent upon individual attending the SNM-TS business meeting to **accept** their award.

2nd Place: $600 for the individual and $400 for the institution. Up to $650 in airfare to the 2000 SNM Annual Meeting in St. Louis, MO to receive your prize. Payment of your registration fee to attend the 2000 SNM Annual Meeting. Your SNM-TS membership dues paid for one year. Airfare and registration contingent upon individual attending the SNM-TS business meeting to accept their award.

3rd Place: $350 for the individual and $250 for the institution. Up to $650 in airfare to the 2000 SNM Annual Meeting in St. Louis, MO to receive your prize. Payment of your registration fee to attend the 2000 SNM Annual Meeting. Your SNM-TS membership dues paid for one year. Airfare and registration contingent upon individual attending the SNM-TS business meeting to accept their award.

4th-10th Place: Your SNM-TS membership dues paid for one year.

Mail 3 copies of your entry information (including this completed form) by December 1, 1999 to:

**Society of Nuclear Medicine**
**1999 PR Stars Contest**
**1850 Samuel Morse Drive**
**Reston, VA 20190-5316**
**Phone: (703) 708-9000, ext. 1223**
**Fax: (703) 708-9018**

Public Relations STARS

Please describe and document your promotional activities and results.
The following point system will be used to determine 10 winners.

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

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

3. How effective were you in reaching the goals of the PR Stars Contest?
   A. Increasing physician referrals? (10 points)
   B. Increasing awareness among healthcare workers? (5 points)
   C. Increasing community awareness? (5 points)
   D. Encouraging career paths? (5 points)
   E. Showing pride in your profession. (5 points)

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

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

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

7. When did your nuclear medicine public relations activity(s) take place? (no points)

8. Please provide a detailed time-line of the planning and implementation of your program. (10 points)

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

Thank you for your entry. On behalf of the SNM-TS and Capintec, Inc., good luck!
And remember, promoting nuclear medicine makes everyone a winner.


Kathleen Krisak, CNMT
1999-2000
Nuclear Medicine Week Chairperson
krisakkk@mail.map.com

Lisa Hazen
2000-2001
Nuclear Medicine Week Chairperson
lmh@freeway.net


Entry Form

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Hospital/Facility _____

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City _____ State _____ Zip _____

Phone _____ Fax _____

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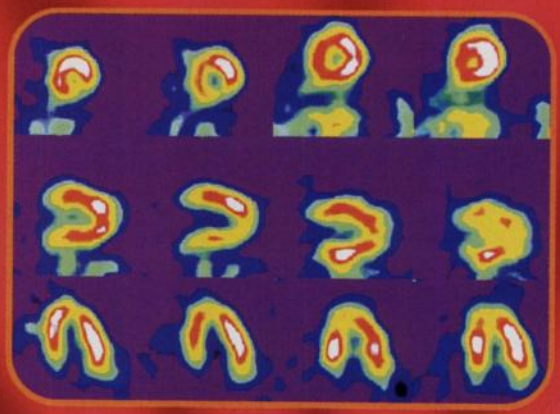

**For more information please contact the SNM PEP Project Coordinator, at (703) 708-9000.**

SNM PEP

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Society of Nuclear Medicine

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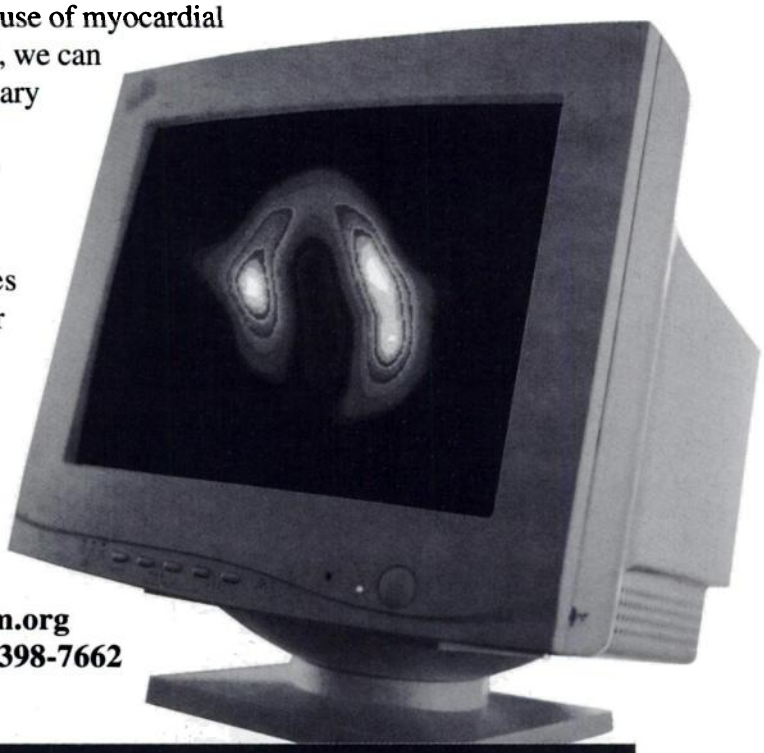

**For more details, contact the SNM Meetings Department at (703) 708-9000 ext. 1229, visit the SNM web site at www.snm.org or call our Fax-on-Demand Service at (800) 398-7662 and enter document 401.**

| Rates | Until Jan. 7, 2000 | On-Site Registration |
|---|---|---|
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| Non-members | $260 | $305 |
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| Non-members | $135 | $165 |
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**Attendees may apply the registration fee toward next year's membership in one of the sponsoring SNM Councils.*

**Society of Nuclear Medicine**

ANNOUNCING

# The American Board of Science In Nuclear Medicine 2000 Certification Examination

## The 2000 examination will be given Sunday, June 4, 2000 in St. Louis, MO in conjunction with the 47th Annual Meeting of the Society of Nuclear Medicine.

The examination is written and consists of two parts —

**Part One** (3.5 hours) assesses knowledge of basic aspects of Nuclear Medicine Science.

**Part Two** (2.5 hours) examines in depth the knowledge of a predetermined subspecialty area of the candidate's choice including:

- Nuclear Medicine Physics and Instrumentation
- Nuclear Pharmaceutical Science and Radiochemistry
- Radiation Protection

**Completed Applications must be postmarked by March 10, 2000.**
**The examination fee is $650 ($550 refundable if you do not qualify).**

For applications and more information, please contact:
ABSNM Exam Coordinator
American Board of Science in Nuclear Medicine
c/o The Society of Nuclear Medicine
1850 Samuel Morse Drive, Reston, Virginia 20190-5316
Tel: (703) 708-9000, ext. 227 • Fax: (703) 708-9013

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Society of Nuclear Medicine

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**Series Editor: Elias H. Botvinick, MD**

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**Contributors in remaining Self-Study Cardiology topics include:**
Drs. Daniel S. Berman, MD; Elias Botvinick, MD; Jamshid Maddahi, MD; H. William Strauss; and Mario S. Verani.

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Society of Nuclear Medicine

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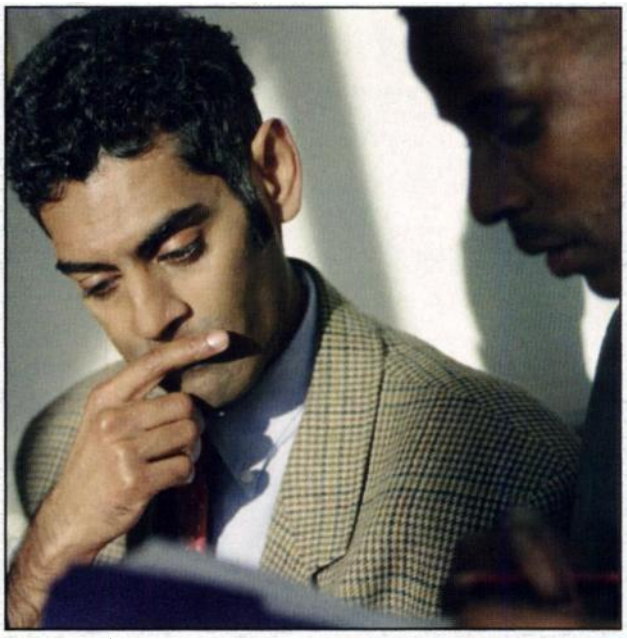

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*June 3-7, 2000 • America's Center • St. Louis, Missouri*

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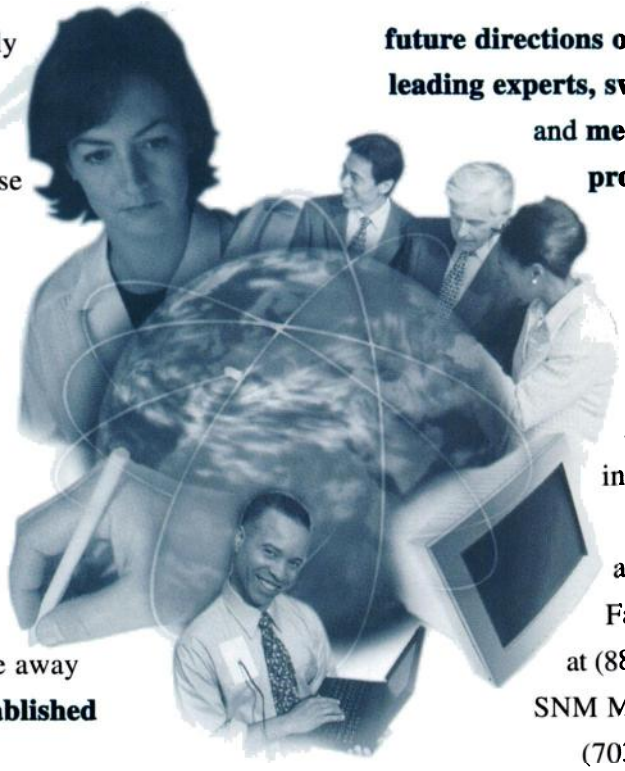

Additional information will be available in January. To obtain more information at that time, visit our web site at www.snm.org, call our Fax-on Demand Service at (888) 398-7662, or call the SNM Meetings Department at (703) 708-9000 ext. 1229.

# SOCIETY OF NUCLEAR MEDICINE (SNM)

47th Annual Meeting, June 3-7, 2000

The SNM Scientific Program and Scientific & Teaching Committees solicit SNM members and non-members to submit abstracts for presentation at the SNM 47th Annual Meeting. The scientific program for next year will include specialties within the following tracks:

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- *Neurosciences*
- *Instrumentation & Data Analysis*
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- *Oncology/Hematology*
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**Abstracts must be received (not postmarked) by the submission deadline. Some institutions and companies have firewalls which may not allow electronic transmission of information. If your institution or company has a firewall which prevents electronic submission of your abstract, you will need to send the diskette on which your abstract is saved by mail to MSS by the submission deadline. Ultimately, if you cannot send your abstract electronically, you remain responsible for meeting the submission deadline, so please plan accordingly.

***The deadline for Technologist Student abstract submissions is February 17 - the option to submit these abstracts electronically will be available only until January 7, although diskettes containing Technologist Student abstracts will be accepted by mail until February 17.

To submit full papers to The Journal of Nuclear Medicine, please contact the editor, Martin P. Sandler, MD, by mail at Society of Nuclear Medicine, 1850 Samuel Morse Dr., Reston, VA 20190-5316.

To submit full papers for the Journal of Nuclear Medicine Technology, please contact the editor, Susan Gilbert, CNMT by mail at 2414 Harney Street, Vancouver, WA 98660.

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**Purpose of fellowship:** To support diagnostic, prognostic or outcomes research focused on the use of nuclear medicine or nuclear cardiology techniques that will assist clinicians and post-menopausal patients with respect to hormone replacement therapy.

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- Residents or fellows in accredited nuclear medicine, cardiology, gynecology, oncology or radiology training programs, or who have just completed training.
- Residents or fellows who have completed at least one year of an accredited residency or fellowship training program.
- Grants are limited to research performed in the United States or Canada.

**Deadline:** February 1, 2000

**Look for more details and application forms in future issues of *The Journal of Nuclear Medicine* and the Society's homepage at www.snm.org.**

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(REQUIRED BY 39 U.S.C. 3685)

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**Interventional Radiologist**
Progressive subspecialized large private practice radiology group is seeking an Interventional Radiologist. The practice is affiliated with a medical school and residency program, thereby offering the benefits of both private practice and the pursuit of academic interests. The practice is located in coastal Virginia with a mild climate and many recreational activities available with the Chesapeake Bay and Atlantic Ocean nearby. Applicant needs training in PET scanning and be a board certified radiologist. Interested persons should send a CV or contact Stephen Carr, MD, Director of Recruiting, Medical Center Radiologists, 6330 North Center Drive, Building 13, Suite 220, Norfolk, VA 23502. Phone: (757) 466-0089. Fax (757) 466-8017.

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A full-time career opportunity exists at the VA North Texas Health Care System, VA Medical Center, Dallas, Texas. Incumbent will serve as a technologist for a large Nuclear Medicine Service. Qualifications: Must be certified in nuclear medicine by the NMTCB or the ARRT. Applicants must be a U.S. citizen and meet the physical requirements of the position. Subject to drug testing. Excellent benefits package.

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***E-mail: jlwu@aol.com***
***or akiharu_otaka@msn.com.***

Application deadline: November 30, 1999.
Funding announcements: by mail.
Fund available: from April 2000.

## Nuclear Radiologist
## Wayne State University

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Interested candidates should send a current curriculum vitae and introductory letter to:

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**Associate Chair, Department of Radiology**
**DRH 3L-8, 4201 St. Antoine**
**Detroit, MI 48201**
**Phone: (313) 745-8585**
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### White River Jct., Vermont

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## Radiochemist

The Department of Nuclear Medicine at Montefiore Medical Center and the Albert Einstein College of Medicine is seeking a qualified Radiochemist. The successful candidate will be responsible for teaching, research and clinical care as they relate to radiopharmaceutical preparation and development. This position will be partially funded through research grants and the candidate is expected to actively seek outside funding. Salary and benefits, include full medical coverage and a generous vacation and holiday package. A minimum of a PhD in a related area is required. EOE.

***Please send Curriculum Vitae to:***

**M. Donald Blaufox, MD, PhD, Chairman**
**Department of Nuclear Medicine**
**1695A Eastchester Rd.**
**Bronx, NY 10461**
**huvane@aecom.yu.edu**

## Supervisory Nuclear Medicine Technologist
### *VA North Texas Health Care System*
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A full-time career opportunity exists at the VA North Texas Health Care System, Dallas, TX. This Health Care System is affiliated with the UTHSC at Dallas. Incumbent will serve as chief Technologist for a large Nuclear Medicine Service.

Qualifications: Must be certified in nuclear medicine by the NMTCB or the ARRT; at least two years of clinical nuclear medicine technology experience; demonstrated supervisory skills; applicants must be a U.S. citizen and meet the physical requirements of the position. Subject to drug testing. Excellent benefits package.

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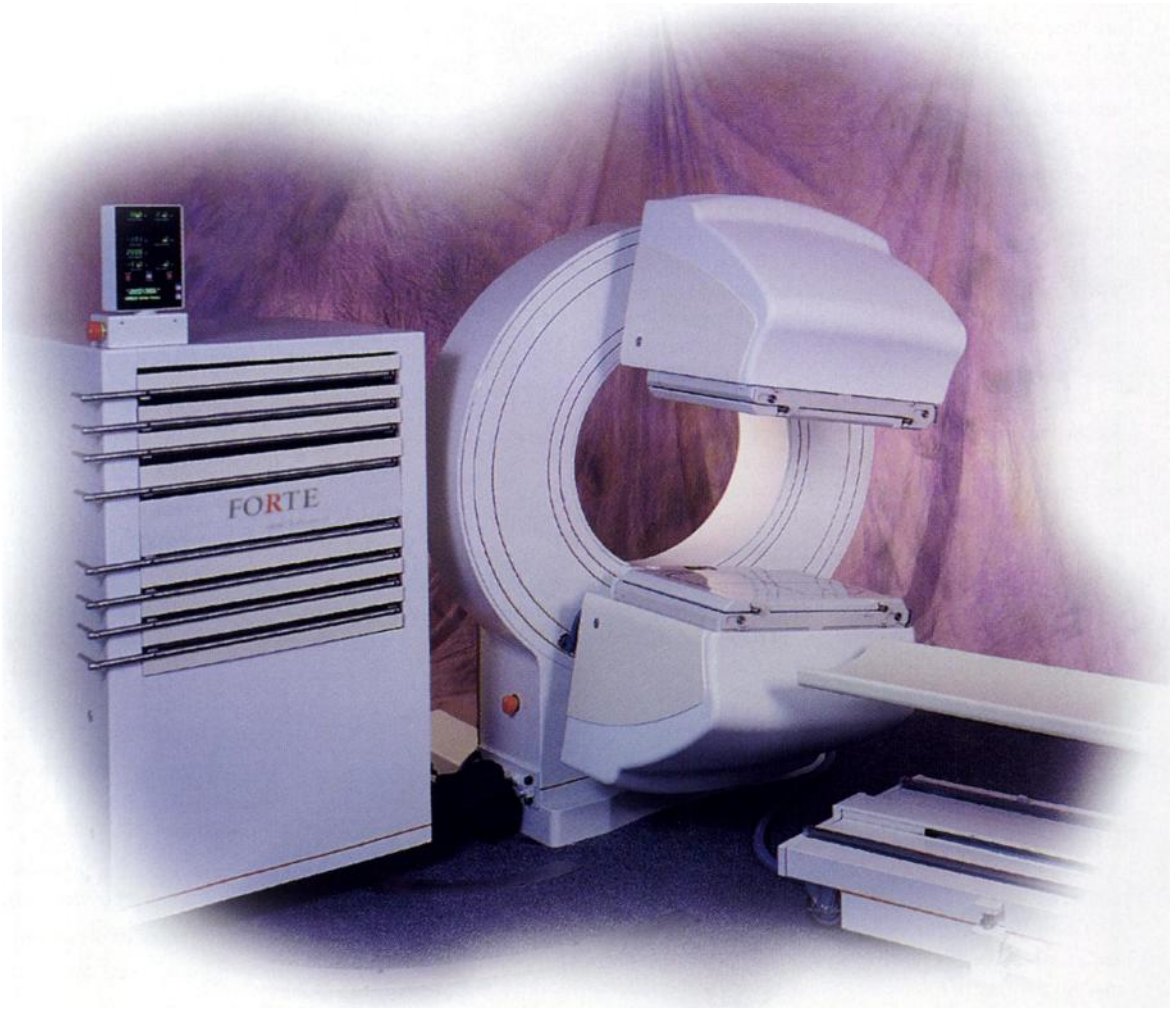


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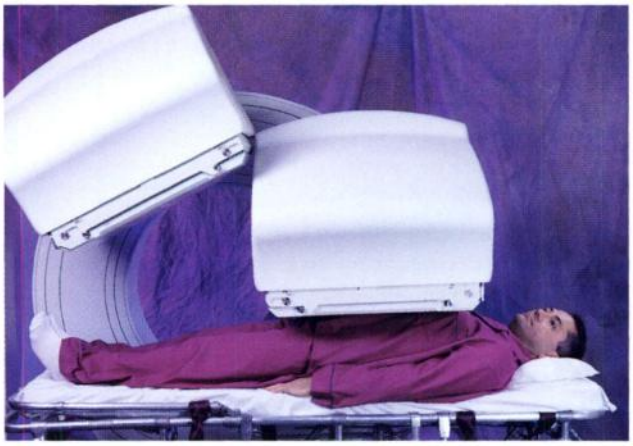

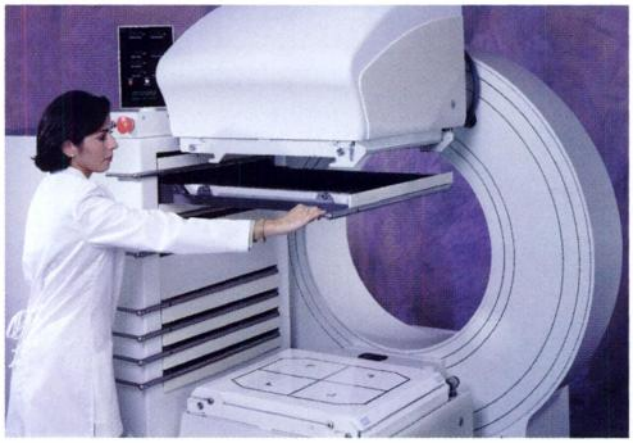

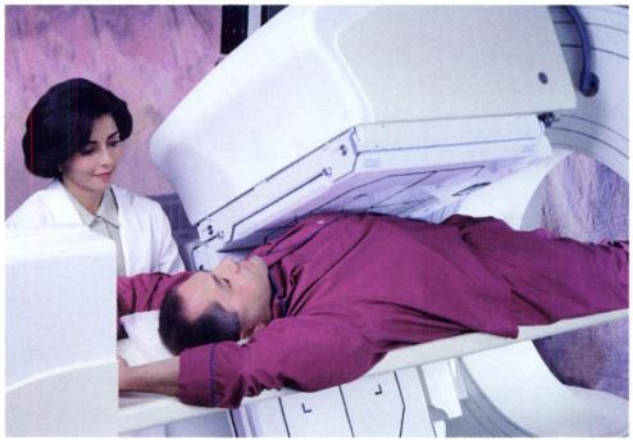

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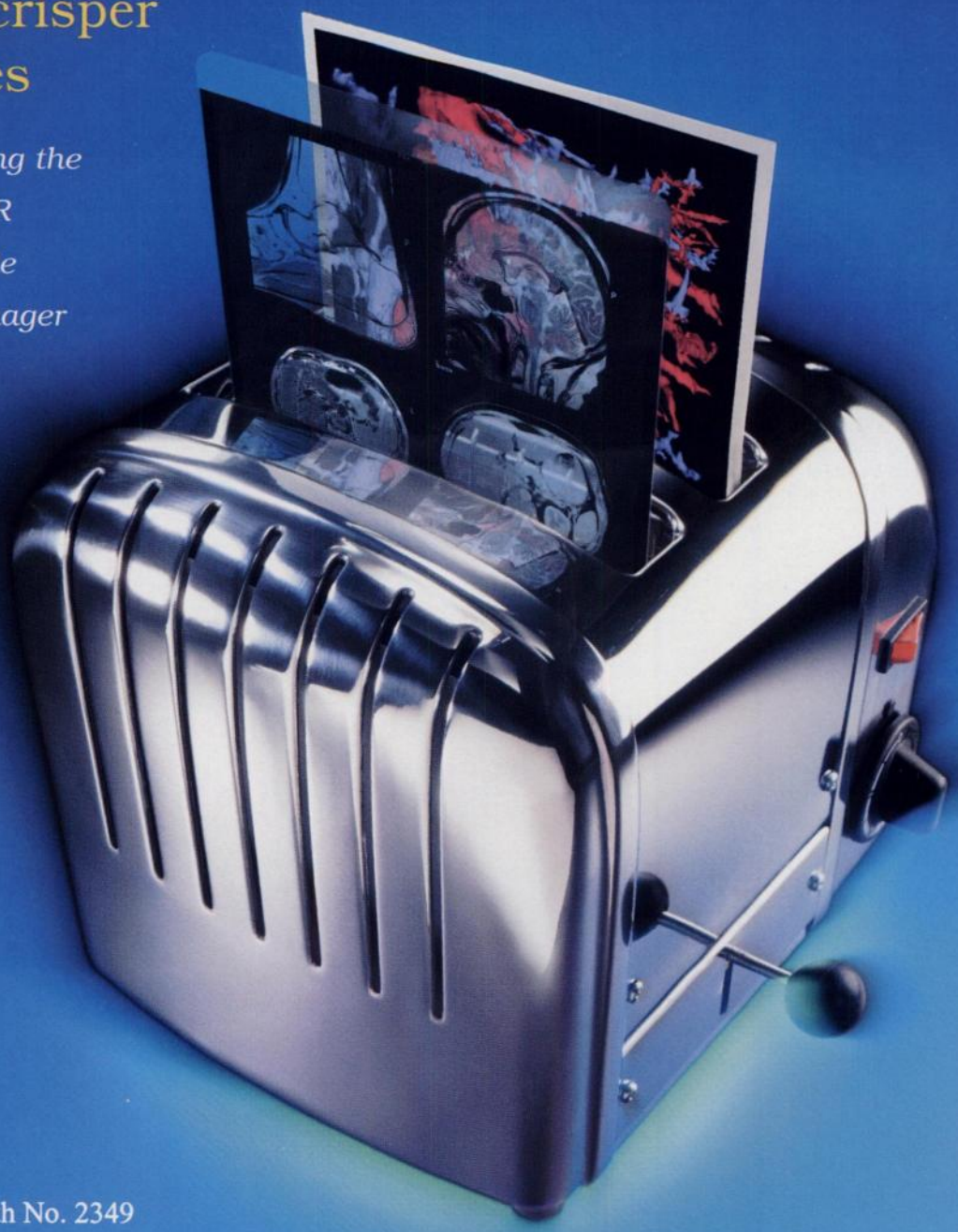

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