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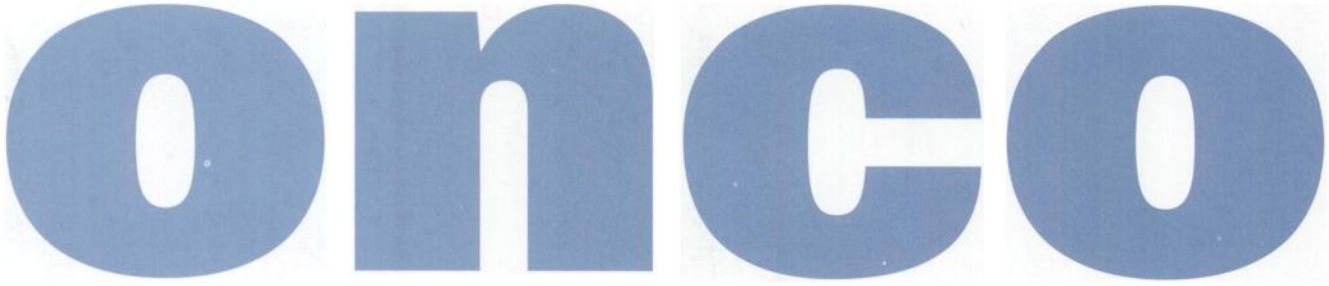

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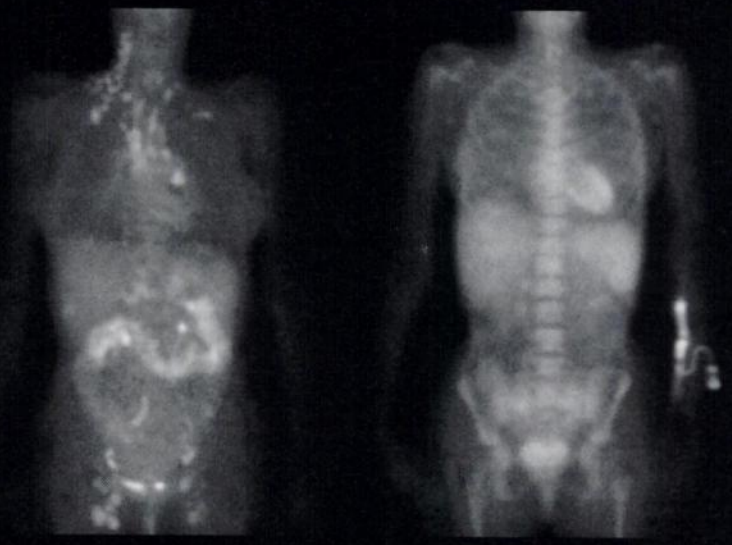

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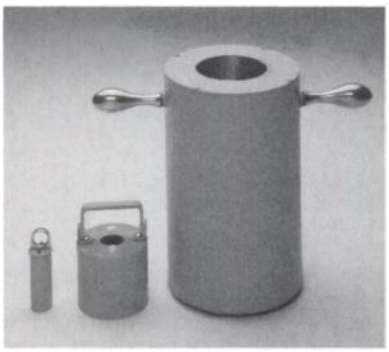

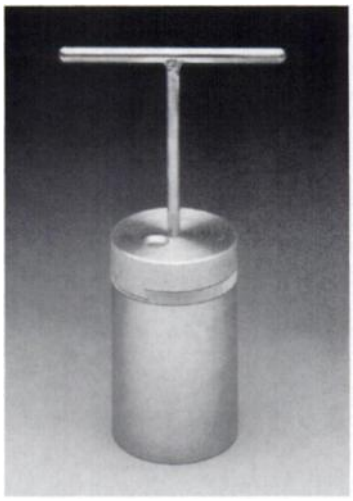

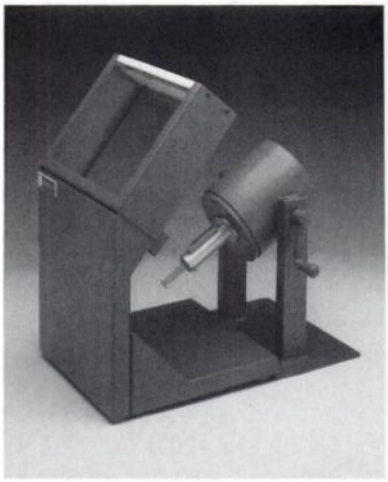

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If your facility is planning to get involved in performing coincidence imaging using F-18 FDG, you must consider the added radiation protection required when dealing with a positron emitting radionuclide. Shielding products used for Tc-99m and other standard Nuclear Medicine nuclides are not designed to fully protect you from the higher energy radiation associated with PET isotopes. Capintec has addressed these new shielding concerns and has already been involved with providing special help and equipment for hospitals and radiopharmacies now involved with 511 keV materials. We have developed an exceptional line of products in response to the need for more appropriate shielding. Please visit our PET/511 Products page on the World Wide Web at www.capintec.com/pet.html, or give us a call to find out what we can do for your Department's needs. Capintec's PET/511 Shielding Products... just another example of our excellence in the field of Nuclear Medicine.

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Technetium Tc99m Tetrofosmin For Injection

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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.

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.

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-43-1011

Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection

Diagnostic Radiopharmaceutical for intravenous use only
Code N166A

DESCRIPTION

The Medi-Physics Myoview™ kit is supplied as a pack of five vials for use in the preparation of a technetium Tc99m tetrofosmin intravenous injection to be used for the scintigraphic delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium. Each vial contains a predispensed, sterile, non-pyrogenic, lyophilized mixture of 0.23 mg tetrofosmin [6,9-bis(2-ethoxyethyl)-3,12-dioxa-6,9-diphosphatetrade-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-gluconate, and 1.8 mg sodium hydrogen carbonate. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

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

CLINICAL PHARMACOLOGY

General

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

Clinical Trials

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

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

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

PRECAUTIONS

General

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

The contents of the Myoview vial are intended only for use in the preparation of technetium Tc99m tetrofosmin injection and are NOT to be administered directly to the patient.

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

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

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

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility.

Tetrofosmin sulphosalicylate was not mutagenic *in vitro* in the Ames test, mouse lymphoma, or human lymphocyte tests, nor was it clastogenic *in vivo* in the mouse micronucleus test.

Pregnancy Category C

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

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse events were evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 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 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 8.61×10^{-3} mSv/MBq and 1.12×10^{-2} mSv/MBq after exercise and rest, respectively.

Manufactured by Amersham International plc
Amersham, United Kingdom

Patent No. 5,045,302 (r)

Distributed by: Medi-Physics, Inc., Amersham Healthcare
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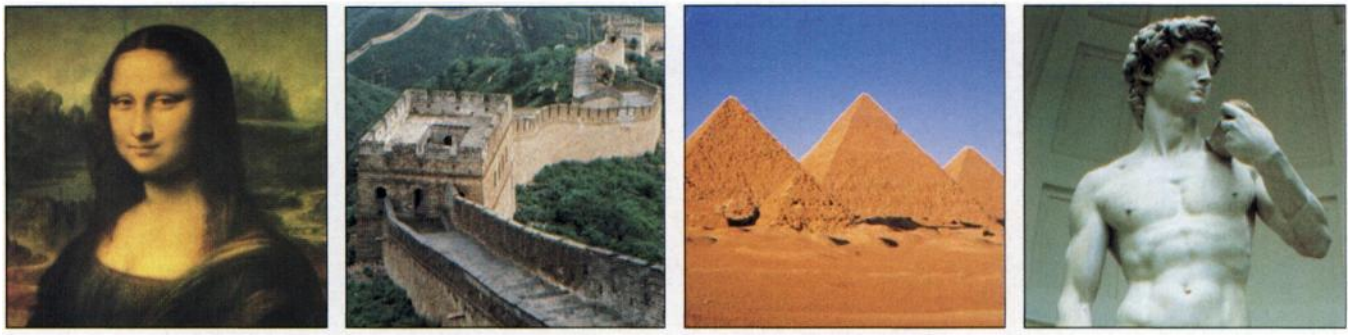

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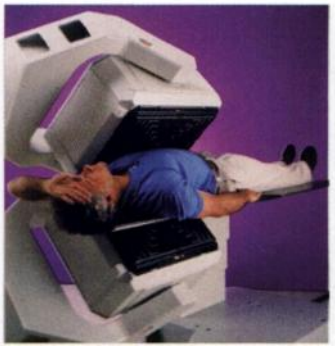

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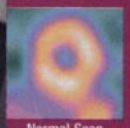
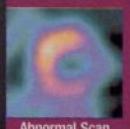
Measure perfusion defects[1-4] with Cardiolite®, and your decision becomes clear.



Normal Scan
Short Axis



Abnormal Scan
Short Axis
Inferolateral Wall
Defect

You need to know. So does he. With Cardiolite®, you get perfusion and function *in a single, noninvasive test*[5,6] for actionable, clinically relevant information to help you decide if cardiac catheterization is appropriate.[7-9]

By measuring perfusion defect size, you can determine extent and severity of CAD.[1-4] From the same test, you also get an extra measure of information with left ventricular function.[10] If his stress study with Cardiolite® is *normal*, you'll know he has a very low risk of a serious cardiac event during the next year.[9,11-13] If his stress study with Cardiolite® is *abnormal*, cath may be the next step,[1-4] especially if EF is low, or if the defect size is moderate to severe.[7-9]

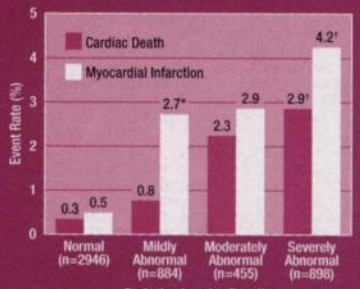
That's the kind of clear, reliable, and reproducible information you need to make patient management decisions with confidence. So, when the question is whether to cath or not, order Cardiolite®. It clears your line of vision.

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

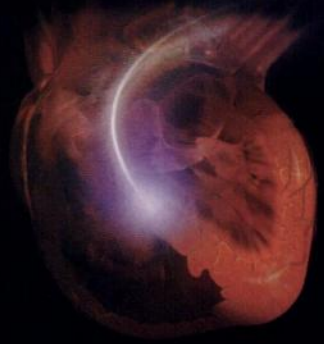
There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi.

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

Rates of Cardiac Death and Myocardial Infarction Per Year (as a Function of Scan Result)[1]



*Statistically significant increase in rate of myocardial infarction versus cardiac death within scan category.
†Statistically significant increase as a function of scan result.
Adapted with permission from Hachamovitch 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.

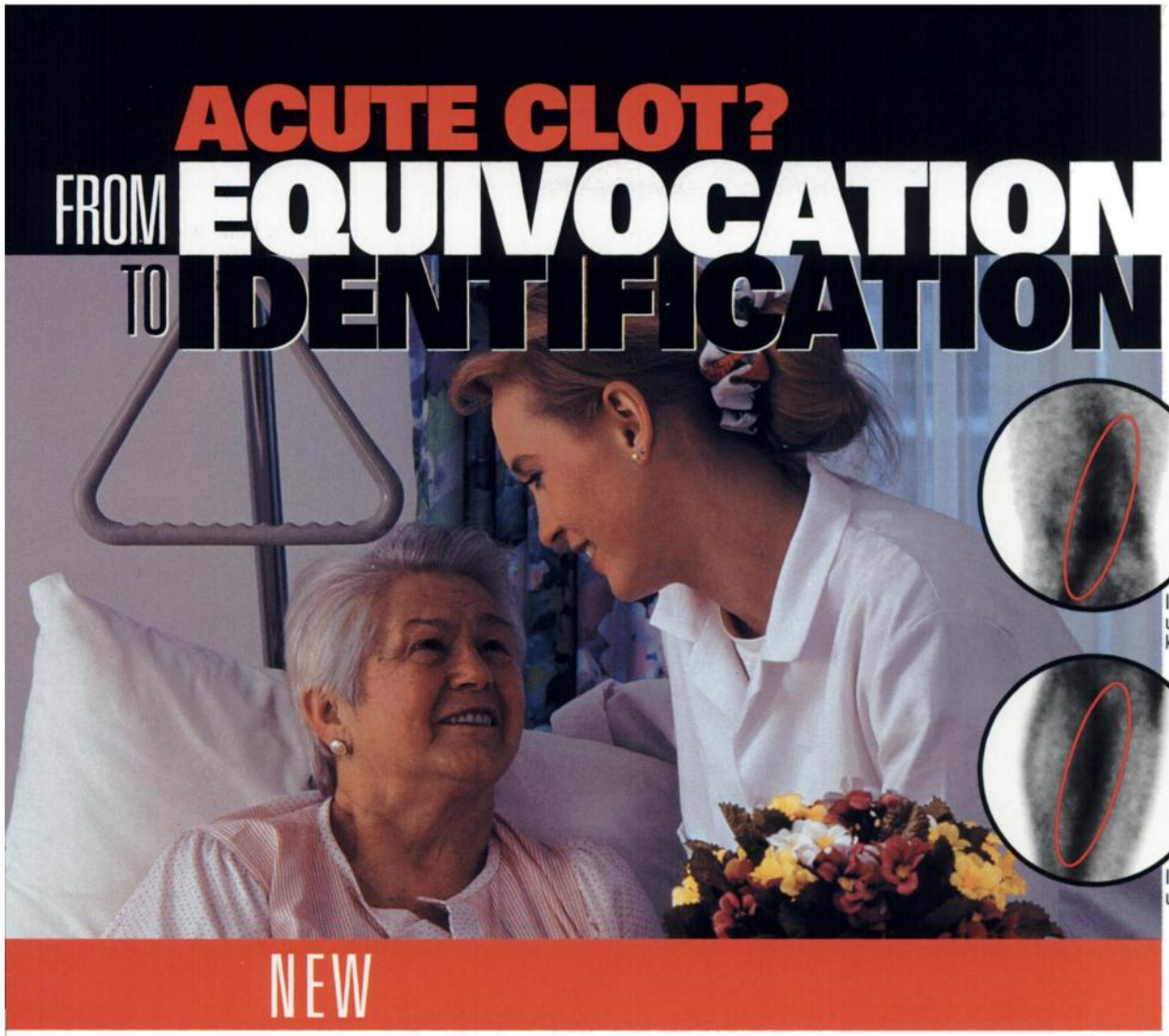
Marketed by: DuPont Pharmaceuticals Company Medical Imaging
331 Treble Cove Road
Billerica, Massachusetts, 01862 USA
For ordering Tel. Toll Free: 800-225-1572
All other business: 800-362-2668
(For Massachusetts and International, call 978-667-9531)

513121-0898 Printed in U.S.A. August 1998

References from ad on previous page: 1. Hachamovitch R, Berman DS, Shaw LJ, et al. Incremental prognostic value of myocardial perfusion single photon emission computed tomography for the prediction of cardiac death. *Circulation.* 1998;97:535-543. 2. Ladenheim ML, Pollock BH, Rozanski A, et al. Extent and severity of myocardial hypoperfusion as predictors of prognosis in patients with suspected coronary artery disease. *J Am Coll Cardiol.* 1986;7(3):464-471. 3. Shaw LJ, Hachamovitch R, Lewin H, et al. Diagnostic and prognostic risk stratification in 7,024 women undergoing SPECT imaging: results from a multicenter prospective registry. *J Nucl Med.* 1998;39(suppl):115P. Abstract 451. 4. Kang X, Berman DS, Van Train KF, et al. Clinical validation of automatic quantitative defect size in rest technetium-99m-sestamibi myocardial perfusion SPECT. *J Nucl Med.* 1997;38:1441-1446. 5. Nichols K, DePuey EG, Rozanski A. Automation of gated tomographic left ventricular ejection fraction. *J Nucl Cardiol.* 1996;3:475-482. 6. Chua T, Kiat H, Germano G, et al. Gated technetium-99m sestamibi for simultaneous assessment of stress myocardial perfusion, postexercise regional ventricular function and myocardial viability. *J Am Coll Cardiol.* 1994;23:1107-1114. 7. Heller GV, Herman SD, Travin MI, et al. Independent prognostic value of intravenous dipyridamole with technetium-99m sestamibi tomographic imaging in predicting cardiac events and cardiac-related hospital admissions. *J Am Coll Cardiol.* 1995;26:1202-1208. 8. Hachamovitch R, Berman DS, Kiat H, et al. Effective risk stratification using exercise myocardial perfusion SPECT in women: gender-related differences in prognostic nuclear testing. *J Am Coll Cardiol.* 1996;28:34-44. 9. Berman DS, Hachamovitch R, Kiat H, et al. Incremental value of prognostic testing in patients with known or suspected ischemic heart disease: a basis for optimal utilization of exercise technetium-99m sestamibi myocardial perfusion single-photon emission computed tomography. *J Am Coll Cardiol.* 1995;26:639-647. 10. Germano G, Vandecker W, Mintz R, et al. Validation of left ventricular volumes automatically measured with gated myocardial perfusion SPECT. *J Am Coll Cardiol.* February 1998:43A. Abstract 1023-133. 11. Stratmann HG, Williams GA, Wittry MD, et al. Exercise technetium-99m sestamibi tomography for cardiac risk stratification of patients with stable chest pain. *Circulation.* 1994;89:615-622. 12. Boyne TS, Koplan BA, Parsons WJ, et al. Predicting adverse outcome with exercise SPECT technetium-99m sestamibi imaging in patients with suspected or known coronary artery disease. *Am J Cardiol.* 1997;79:270-274. 13. Iskander S, Iskandrian AE. Risk assessment using single-photon emission computed tomographic technetium-99m sestamibi imaging. *J Am Coll Cardiol.* 1998;32:57-62.

ACUTE CLOT?

FROM EQUIVOCATION TO IDENTIFICATION



Increased **tracer** uptake **at** knee/popliteal **vein**

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

NEW

AcuTect™

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

The first imaging modality to target *acute* DVT

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

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

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

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

For customer service, call 1-877-DIATIDE.

The difference is acute.

Diatide, Inc.

WE'VE GOT YOUR SOLUTIONS. Nycomed Amersham

Please see brief summary of prescribing information on following page.

NEW AcuTect

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

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please consult Full Product Information before using.

DESCRIPTION

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

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

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

CONTRAINDICATIONS: None known.

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

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

PRECAUTIONS

General

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

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

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

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

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

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

Information for Patients

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

Laboratory Tests

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

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

Drug Interactions

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy

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

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

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

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

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

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

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

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

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

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

Lower Extremity Imaging

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

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

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

RADIATION DOSIMETRY

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

Table 2: Radiation Absorbed Doses for a 70kg Adult

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

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

HOW SUPPLIED

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

Storage

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

The kit should be protected from light.

Rx only

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

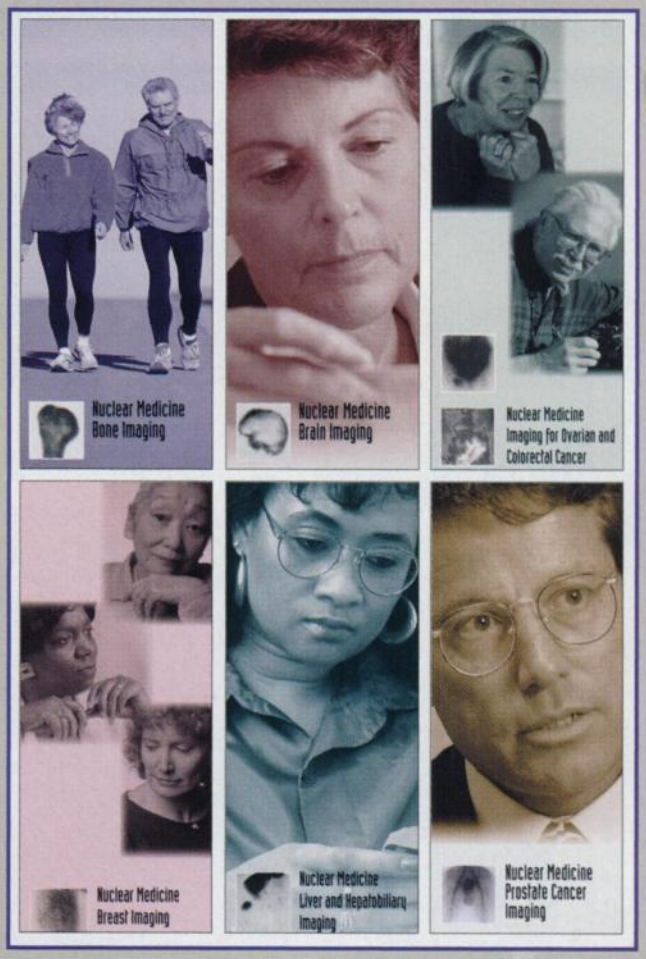
Rev. September 1998
Distributed by: Diatide, Inc. and Nycomed Amersham
60-801971

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

The difference is acute.

Educate Your Patients

SNM Patient Pamphlets Offer the Reassurance Your Patients Need



As a clinician, you know nuclear medicine procedures are safe and effective. But you also know that patients are sometimes uneasy about them. Give your patients peace of mind by providing them with concise and thorough information. Whatever your most commonly ordered procedure, you'll find an SNM Patient Pamphlet that will address your patient education needs.

Start with "The Benefits of Nuclear Medicine." This pamphlet defines commonly performed nuclear medicine procedures, and includes a question and answer section geared for the patient.

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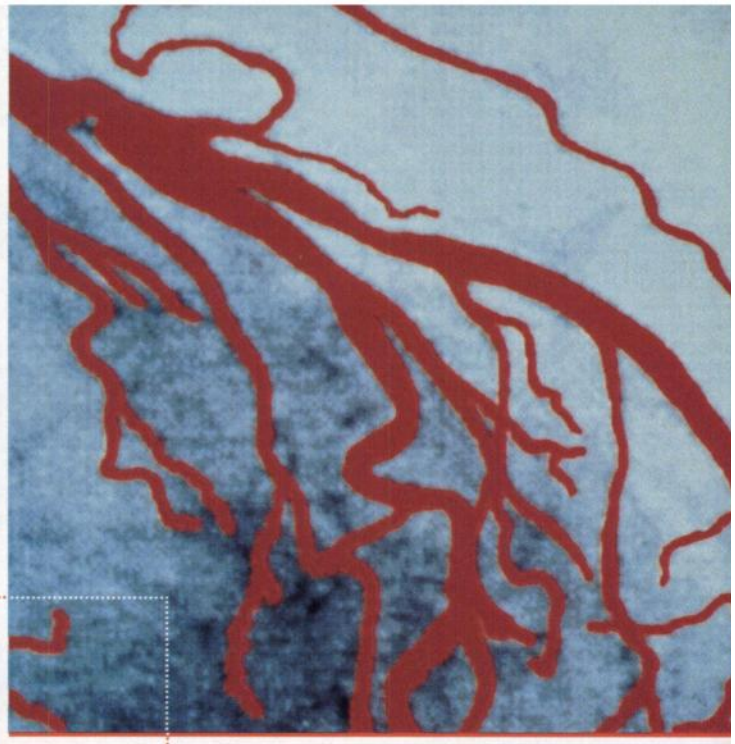
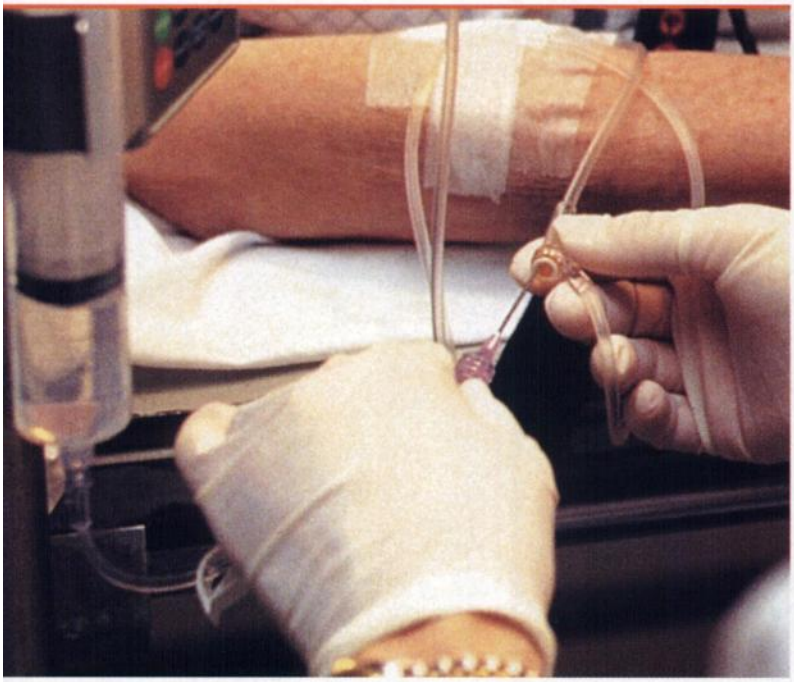
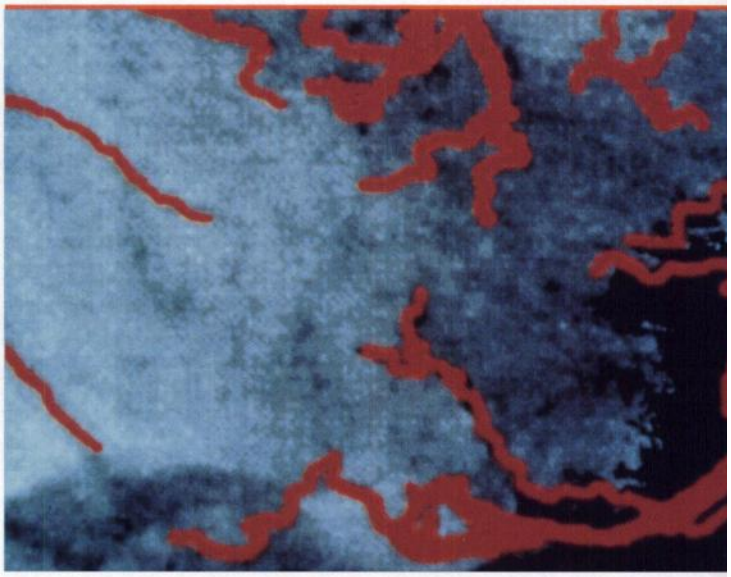
fast START



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

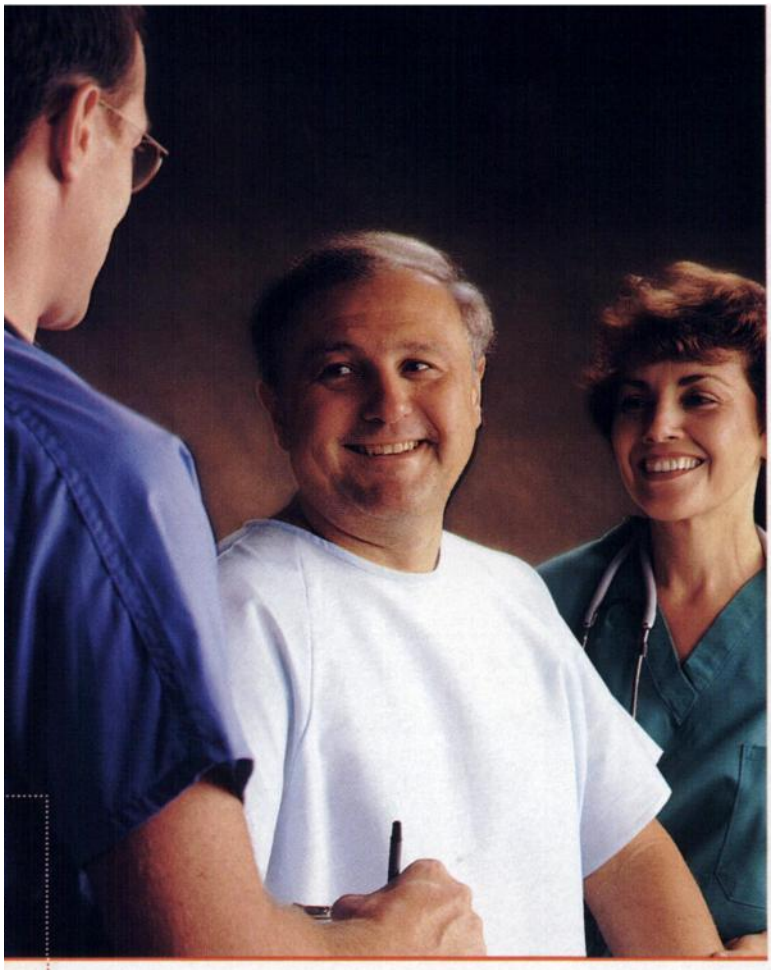
- Consistently produces maximal vasodilation.
- Blood flow increases 3- to 4-fold over baseline.[1]

RAPID RETURN

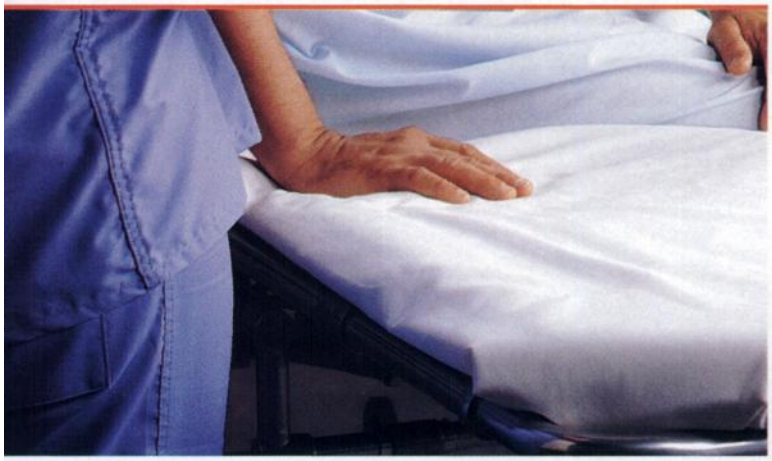
- <10-second half-life.
- Side effects usually resolve quickly and spontaneously.*

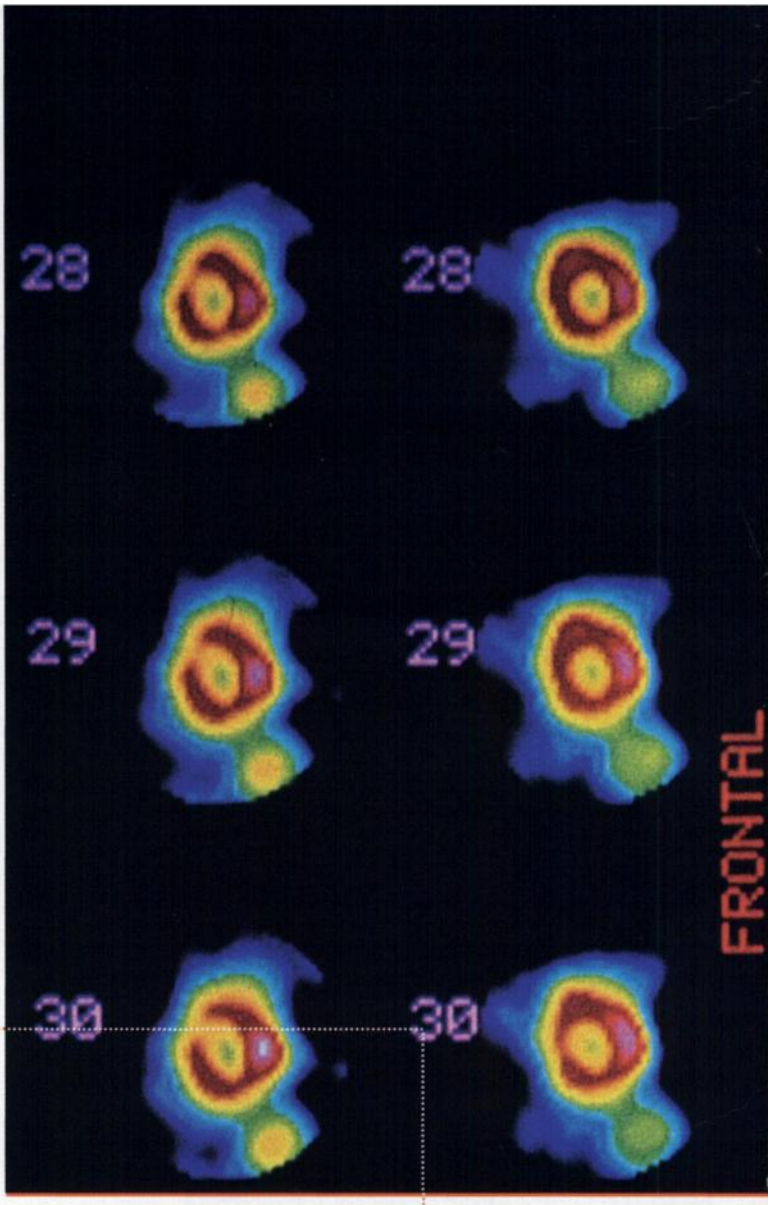
STRONG FINISH

- Imaging comparable to exercise.
- Lower cost-per-case than dipyridamole.[2]

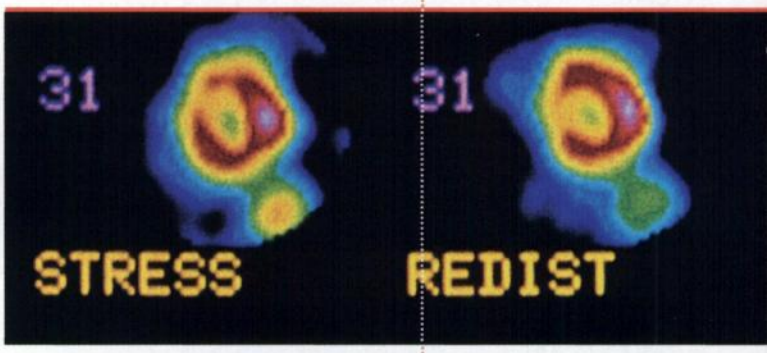


rapid RETURN





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®

adenosine

Circle Reader Service No. 50

AS510

2/98

www.adenoscan.com

BRIEF SUMMARY

ADENOSCAN®
adenosine

For Intravenous Infusion Only

DESCRIPTION

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

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

Each Adenoscan vial contains a sterile, non-pyrogenic solution of adenosine 3 mg/mL and sodium chloride 9 mg/mL in Water for Injection, q.s. The pH of the solution is between 4.5 and 7.5.

INDICATIONS AND USAGE:

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

CONTRAINDICATIONS:

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

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

WARNINGS:

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

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

Sinoatrial and Atrioventricular Nodal Block

Adenoscan (adenosine) exerts a direct depressant effect on the SA and AV nodes and has the potential to cause first-, second- or third-degree AV block, or sinus bradycardia. Approximately 6.3% of patients develop AV block with Adenoscan, including first-degree (2.9%), second-degree (2.6%) and third-degree (0.8%) heart block. All episodes of AV block have been asymptomatic, transient, and did not require intervention. Adenoscan can cause sinus bradycardia. Adenoscan should be used with caution in patients with pre-existing first-degree AV block or bundle branch block and should be avoided in patients with high-grade AV block or sinus node dysfunction (except in patients with a functioning artificial pacemaker). Adenoscan should be discontinued in any patient who develops persistent or symptomatic high-grade AV block. Sinus pause has been rarely observed with adenosine infusions.

Hypotension

Adenoscan (adenosine) is a potent peripheral vasodilator and can cause significant hypotension. Patients with an intact baroreceptor reflux mechanism are able to maintain blood pressure and tissue perfusion in response to Adenoscan by increasing heart rate and cardiac output. However, Adenoscan should be used with caution in patients with autonomic dysfunction, stenotic valvular heart disease, pericarditis or pericardial effusions, stenotic carotid artery disease with cerebrovascular insufficiency, or uncorrected hypovolemia, due to the risk of hypotensive complications in these patients. Adenoscan should be discontinued in any patient who develops persistent or symptomatic hypotension.

Hypertension

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

Bronchoconstriction

Adenoscan (adenosine) is a respiratory stimulant (probably through activation of carotid body chemoreceptors) and intravenous administration in man has been shown to increase minute ventilation (Ve) and reduce arterial PCO_2 causing respiratory alkalosis. Approximately 28% of patients experience breathlessness (dyspnea) or an urge to breathe deeply with Adenoscan. These respiratory complaints are transient and only rarely require intervention. Adenosine administered by inhalation has been reported to cause bronchoconstriction in asthmatic patients, presumably due to mast cell degranulation and histamine release. These effects have not been observed in normal subjects. Adenoscan has been administered to a limited number of patients with asthma and mild to moderate exacerbation of their symptoms has been reported. Respiratory compromise has occurred during adenosine infusion in patients with obstructive pulmonary disease. Adenoscan should be used with caution in patients with obstructive lung disease not associated with bronchoconstriction (e.g., emphysema, bronchitis, etc.) and should be avoided in patients with bronchoconstriction or bronchospasm (e.g., asthma). Adenoscan should be discontinued in any patient who develops severe respiratory difficulties.

PRECAUTIONS:

Drug Interactions

Intravenous Adenoscan (adenosine) has been given with other cardioactive drugs (such as beta adrenergic blocking agents, cardiac glycosides, and calcium channel blockers) without apparent adverse interactions, but its effectiveness with these agents has not been systematically evaluated.
Because of the potential for additive or synergistic depressant effects on the SA and AV nodes, however, Adenoscan should be used with caution in the presence of these agents. The vasoactive effects of Adenoscan are inhibited by adenosine receptor antagonists, such as alkylxanthines (e.g., caffeine and theophylline). The safety and efficacy of Adenoscan in the presence of these agents has not been systematically evaluated. The vasoactive effects of Adenoscan are potentiated by nucleoside transport inhibitors, such as dipyridamole. The safety and efficacy of Adenoscan in the presence of dipyridamole has not been systematically evaluated. Whenever possible, drugs that might inhibit or augment the effects of adenosine should be withheld for at least five half-lives prior to the use of Adenoscan.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies in animals have not been performed to evaluate the carcinogenic potential of Adenoscan (adenosine). Adenosine was negative for genotoxic potential in the Salmonella (Ames Test) and Mammalian Microsome Assay.
Adenosine, however, like other nucleosides at millimolar concentrations present for several doubling times of cells in culture, is known to produce a variety of chromosomal alterations. In rats and mice, adenosine administered intraperitoneally once a day for five days at 50, 100, and 150 mg/kg [10-30 (rats) and 5-15 (mice) times human dosage on a mg/M^2 basis] caused decreased spermatogenesis and increased numbers of abnormal sperm, a reflection of the ability of adenosine to produce chromosomal damage.

Pregnancy Category C

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

Pediatric Use

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

ADVERSE REACTIONS:

The following reactions with an incidence of at least 1% were reported with intravenous Adenoscan among 1421 patients enrolled in controlled and uncontrolled U.S. clinical trials. Despite the short half-life of adenosine, 10.6% of the side effects occurred not with the infusion of Adenoscan but several hours after the infusion terminated. Also, 8.4% of the side effects that began coincident with the infusion persisted for up to 24 hours after the infusion was complete. In many cases, it is not possible to know whether these late adverse events are the result of Adenoscan infusion.

Flushing	44%	Gastrointestinal discomfort	13%	Second-degree AV block	3%
Chest discomfort	40%	Lightheadedness/dizziness	12%	Paresthesia	2%
Dyspnea or urge to breathe deeply	28%	Upper extremity discomfort	4%	Hypotension	2%
Headache	18%	ST segment depression	3%	Nervousness	2%
Throat, neck or jaw discomfort	15%	First-degree AV block	3%	Arrhythmias	1%

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

Body as a Whole: back discomfort; lower extremity discomfort; weakness.

Cardiovascular System: nonfatal myocardial infarction; life-threatening ventricular arrhythmia; third-degree AV block; bradycardia; palpitation; sinus exit block; sinus pause; sweating; T-wave changes, hypertension (systolic blood pressure > 200 mm Hg).

Central Nervous System: drowsiness; emotional instability; tremors.

Genital/Urinary System: vaginal pressure; urgency.

Respiratory System: cough.

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

OVERDOSAGE:

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

DOSAGE AND ADMINISTRATION:

For intravenous infusion only.

Adenoscan should be given as a continuous peripheral intravenous infusion.

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

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

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

The safety and efficacy of Adenoscan administered by the intracoronary route have not been established.

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

CAUTION: Federal law prohibits dispensing without prescription.

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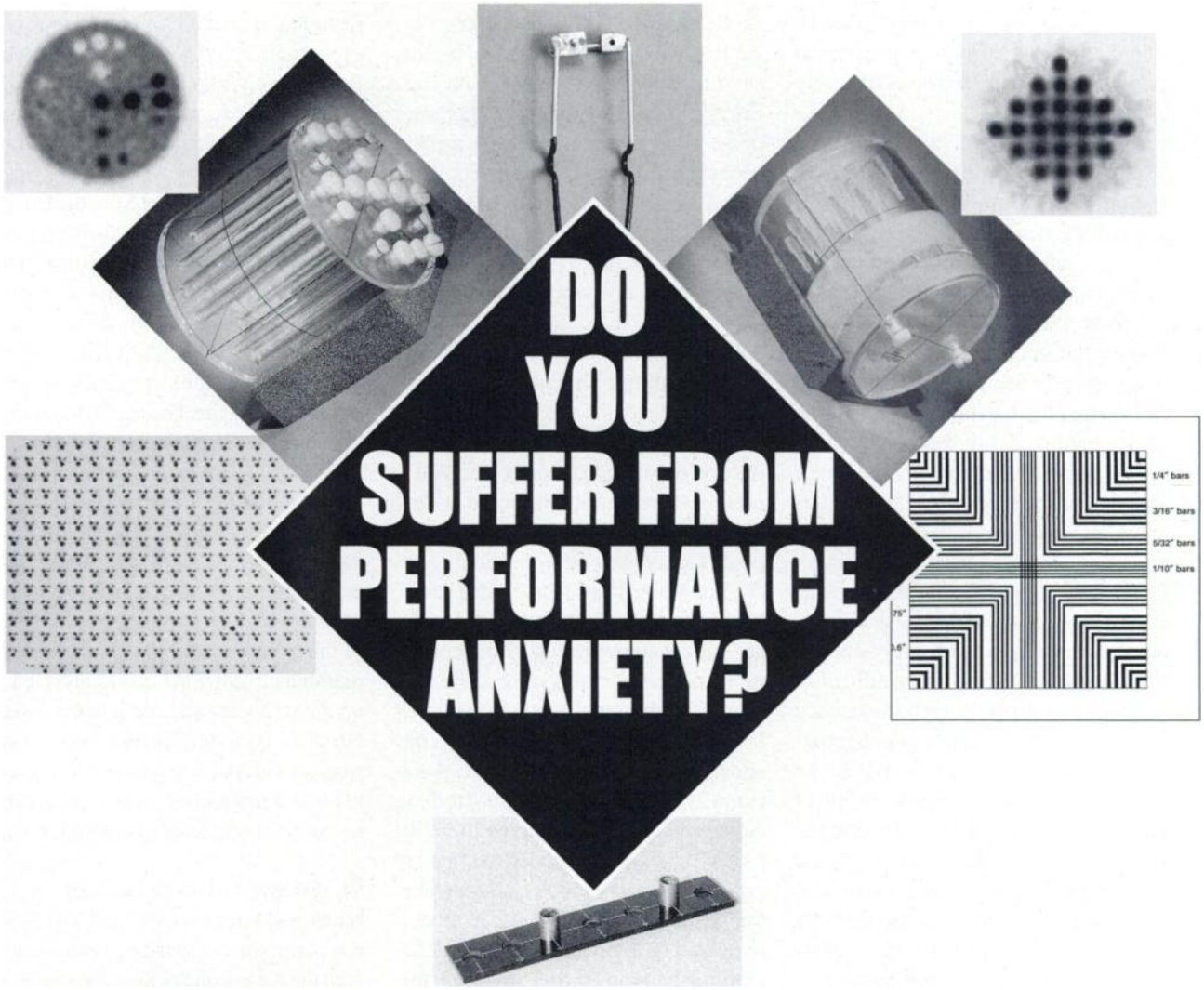

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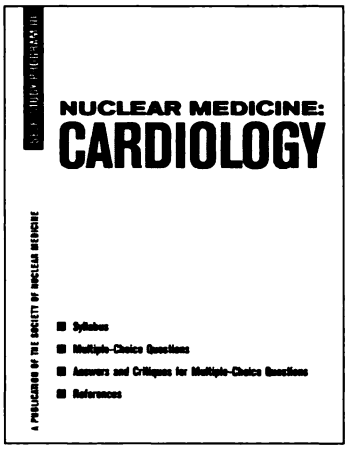

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Price: $25 (SNM members); $35 (nonmembers)

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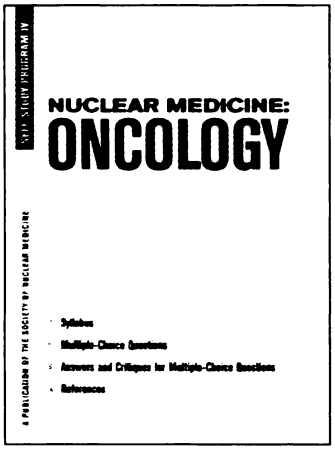

Management of the cancer patient has significantly grown with better diagnostic techniques and chemotherapeutic agents. Learn about these exciting advances in nuclear oncologic imaging with the Self-Study Program series in Oncology. These Self-Study Programs offer an innovative package and approach to ensure that you receive timely, targeted materials as soon as they're available.

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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)
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1999-2000 Fellowship Program for

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The Society of Nuclear Medicine, in partnership with the Medical Imaging Division of DuPont Pharmaceuticals Company, is offering a new one year fellowship available July 1, 1999 in the amount of $30,000.00 to support diagnostic, prognostic or outcomes research focused on the use of Nuclear Medicine or Nuclear Cardiology techniques which will assist clinicians and post-menopausal patients with respect to hormone replacement therapy. Primary research areas of the fellowship are known or suspected coronary artery disease, elevated serum cholesterol, breast cancer and/or osteoporosis.

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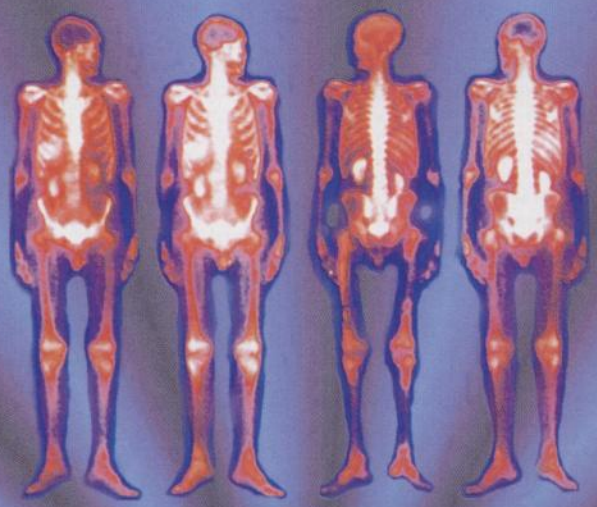

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46th Annual Meeting

LOS ANGELES, CALIFORNIA

June 6 -10, 1999

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1850 Samuel Morse Drive
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Phone: (703) 708-9000 x229
Fax: (703) 709-9274
www.snm.org

LOCATION:

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

DEADLINES:

Pre-Registration Ends:	April 29, 1999
Last Day for Housing Reservations:	April 29, 1999

REGISTRATION FEES:

Categorical

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

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

Categoricals

Sunday, June 6, 1999	**Pre-Registration**	**On-Site**
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Continuing Education

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

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Physician/Scientist/Pharmacist	$530	$590
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Companion	$55	$55

EXHIBITS:

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

HOW TO OBTAIN PRE-REGISTRATION AND HOUSING FORMS:

1. The SNM Web Site, www.snm.org
2. Fax-On-Demand*, 888-398-7662 or 703-7531-1514
3. The Journal of Nuclear Medicine, February Issue
4. Journal of Nuclear Medicine Technology, March Issue

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* *Fax-on-Demand is an automated system that faxes you those portions of the Annual Meeting Preview you request. If you do not know exactly which portion you would like to receive (or what is available), you can request an index of documents when prompted by the system.*

WHERE DO YOU FIT IN?

WHAT IS THE UA DATA BASE?

The Commission on Health Care Policy and Practice in conjunction with the SNM Technologist Task Force on Utilization Data, has developed a quarterly survey on SNM's website. Participants enter data quarterly.

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
- Active general medicine and surgical beds
- Outpatient encounters (visits)
- Physician, technologist and clerical FTEs
- Planar, SPECT, PET Hybrid gamma cameras and PET scanners
- Inpatient and outpatient procedures for a selected set of commonly used nuclear medicine CPT-4 codes

WHY SHOULD YOU PARTICIPATE?

Participants receive standard reports on utilization by procedure, place of service, type of patient, etc.

Participants will be able to compare their facility data with others in the region and with the national (global) averages.

Subscribers may query reports on-line or receive printed reports quarterly via mail. This is a free service. As long as you input your data quarterly, you will be able to obtain data and reports.

All information is confidential.

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

UTILIZATION DATABASE ANALYSIS

Positions Needed

Research Associate in Nuclear Medicine
Position open on 7/01/99 for a Board Certified NM physician. An in-depth experience in neuroreceptor PET imaging and in image analysis using SPM, Matlab and Analyze, and extensive computer knowledge of PC, Mac and Unix systems is required. Send inquiries to: J.J. Frost, MD, PhD, Johns Hopkins University SOM, 600 N. Wolfe St., Baltimore, MD 21287.

Radiochemist
The Division of Cardiology at the College of Physicians & Surgeons of Columbia University is recruiting a radiochemist for research and development of positron-emitting radiotracers for cardiac PET applications. The successful candidate will receive an appointment at P&S commensurate with academic background and experience. Applicants must have a strong, direct background in both synthetic chemistry as well as labeling with positron emitters. Please send a CV and 3 references to Steven Bergmann, MD, PhD, Columbia University, College of Physicians & Surgeons, PH 10-Stem 405, 630 W. 168th St., New York, NY 10032. Fax: (212) 305-9882. Email: srb40@columbia.edu. We take affirmative action toward equal opportunity.

Research Associate–Yale University
Research in radiochemistry in PET with application to the brain and positron emission tomography. Candidate should have background in: radiochemistry and organic synthesis of chemical precursors and a record of independent research. Prefer PhD in Chemistry. If interested and qualified, please submit a scannable resume referencing Source Code EZSNUCLMED: Ms. A. Michaels, Department of Human Resources (Source Code EZSNUCLMED), Yale School of Medicine, P.O. Box 208344, New Haven, CT 06520-8344. Fax (203) 432-9817.

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Nuclear Medicine Technologist
The Department of Veterans Affairs, Medical and Regional Office Center, White River Junction, Vermont is currently recruiting for a full-time Nuclear Medicine Technologist certified or eligible for exam in AART or NMTCB. Salary range $31,897-$41,470. Apply to Human Resources Management Service, VAM & ROC, 215 N. Main St., White River Junction, VT 05009. Phone: (802) 296-5144. EOE.

Nuclear Medicine Residency/Fellowship
The Harvard Medical School, Joint Program in Nuclear Medicine invites applications for one-year fellowship and two-year residency positions beginning July 1st, 1999 and 2000. Please direct your inquires to: Cathy O'Callaghan, Training Program Coordinator, Joint Program in Nuclear Medicine, Children's Hospital, 300 Longwood Ave., Boston, MA 02115 or by e-mail at: ocallaghan@a1.tch.harvard.edu.

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Department of Veterans Affairs Medical Center
Dallas, TX 75216

Applications are being sought for a full-time Nuclear Medicine Staff Physician, Veterans Affairs Medical Center, Dallas, TX. The position includes an academic appointment in the Department of Radiology, University of Texas Southwest Medical School.

Applications must be board eligible or board certified in Nuclear Medicine. Cardiac, Therapeutic and SPECT experience as well as strong research capabilities required.

Responsibilities include teaching Radiology and Nuclear Medicine residents. A CV and 3 letters of reference should be sent to: Ana Mello, MD, Chief, Nuclear Medicine Service, Veterans Affairs Medical Center, 4500 Lancaster Rd., Dallas, TX 75216.

NO TELEPHONE CALLS ACCEPTED.

Equal Opportunity Employer
Applicants Subject to Drug Testing
Smoke-Free Facility

Nuclear Medicine Bone Imaging

As a clinician, you know nuclear medicine procedures are safe and effective. But you also know that patients are sometimes uneasy about them. Give your patients peace of mind by providing them with concise and thorough information.

Since bone scans are used to detect arthritis, osteoporosis, fractures and sports injuries, as well as unexplained bone pain, bone imaging is one of the most commonly performed nuclear medicine tests. The *Nuclear Medicine Bone Imaging* pamphlet prepares patients for the test, explains exam procedures and informs patients what needs to be done after the test.

To order, simply contact SNM's book distributor, Matthews Medical Books, at their toll free number (800) 633-2665 (non-U.S. 314-432-1401), or Fax: (314) 432-7044. Check SNM's on-line book catalog (www.snm.org) for future patient pamphlets and books.

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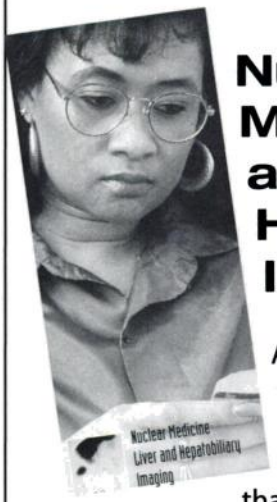

Nuclear Medicine Liver and Hepatobiliary Imaging

As a clinician, you know nuclear medicine procedures are safe and effective. But you also know that patients are sometimes uneasy about them. Give your patients peace of mind by providing them with concise and thorough information.

This pamphlet describes what patients will experience when they have a nuclear medicine liver or hepatobiliary scan. This pamphlet explains liver scans and how they help diagnose hepatic disorders such as cirrhosis, hepatitis, tumors, as well as problems in other parts of the digestive system. The *Nuclear Medicine Liver and Hepatobiliary Imaging* pamphlet provides instructions to the patient before, during and after their exam.

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E-mail the Publications Department for pamphlet samples at ssilver@snm.org. Whatever your most commonly ordered procedure, you'll find an SNM patient pamphlet that will address your patient education needs.

SNM Patient Pamphlets Offer the Reassurance Your Patients Need.

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

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

MIRD CELLULAR S VALUES

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

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

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

To order, simply call Matthews Medical Books at their toll free number:

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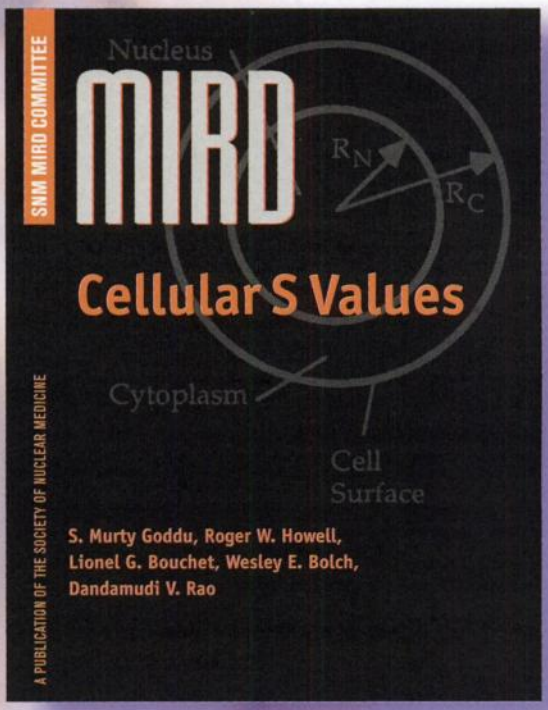


MIRD PRIMER FOR ABSORBED DOSE CALCULATIONS

Revised Edition

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

MIRD RADIONUCLIDE DATA AND DECAY SCHEMES

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

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

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

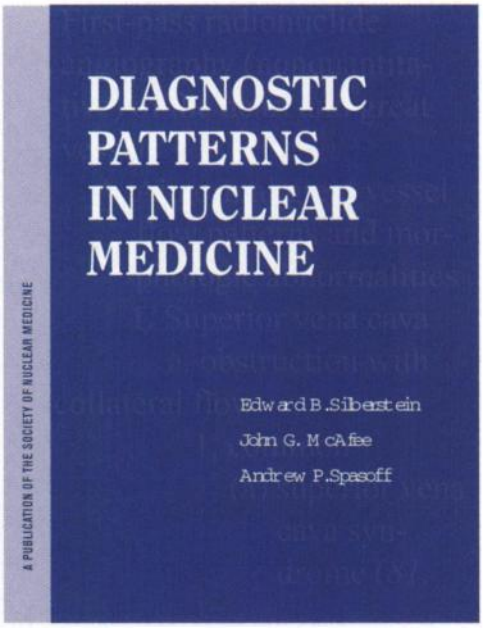
This reference book provides a complete list of differential diagnoses for virtually every pattern described in modern nuclear medicine scintigraphy, including the latest findings in nuclear cardiology, PET, antibody and somatostatin receptor imaging. A full list of all diagnostic patterns reported for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

Diagnostic Patterns in Nuclear Medicine assists in image interpretation by providing complete diagnoses for every scintigraphic pattern. All entries are documented by published references. Organization by organ system provides an easy-to-find, detailed differential diagnosis.

The clinician simply looks up any scintigraphic finding to determine possible causes of that finding, ranked in order of probability, making *Diagnostic Patterns in Nuclear Medicine* the most complete referenced diagnostic guide available.

ISBN: 0-932004-69-5

Price: $45 (members); $63 (nonmembers).



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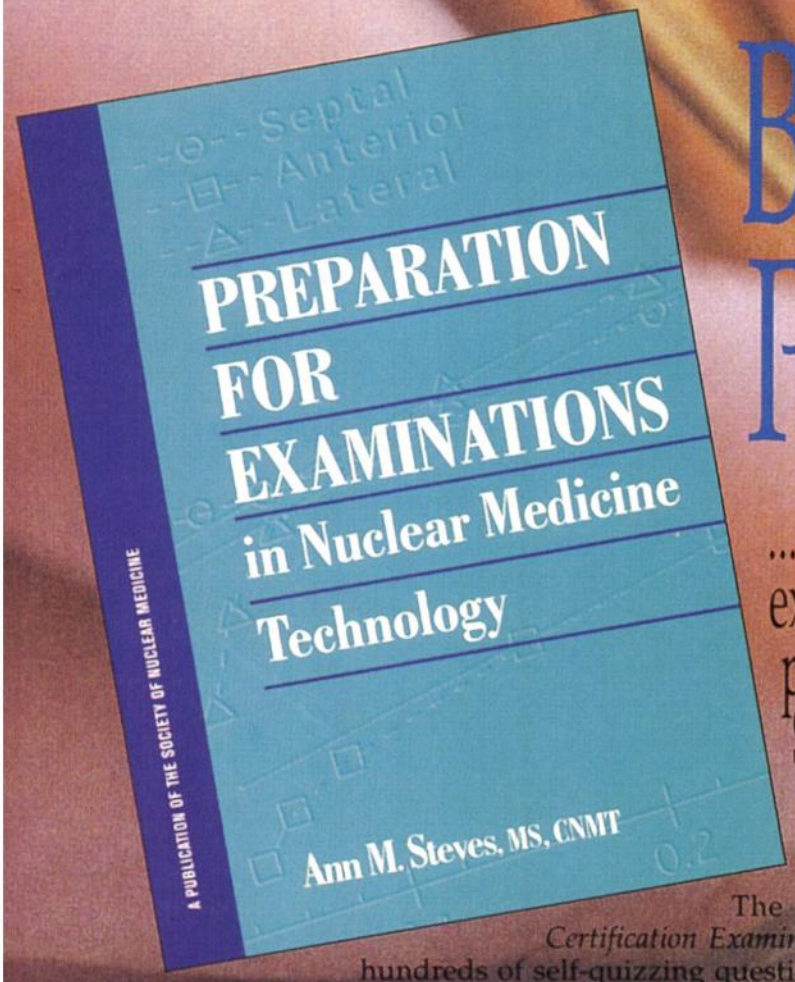

Boost Your Performance...

... on national certification examinations, with two new exam preparation texts from the Society of Nuclear Medicine Technologist Section—

The brand-new, illustrated *Preparation for Certification Examinations in Nuclear Medicine Technology* contains hundreds of self-quizzing questions and answers to help you perform at your peak. Mirroring the structure of those on national certification exams, these multiple-choice questions cover–

Radiopharmacy • Radiation Safety • Instrumentation • Patient Care • Clinical Procedures

Each answer is accompanied with thorough, easy-to-understand explanations and source references for more information.

And if your library doesn't include the recently updated *The Review of Nuclear Medicine Technology*, you're missing the single most effective exam study text you can own. New material includes the latest information on NRC regulations, recently introduced radiopharmaceuticals, and an expanded section on the rapidly growing field of nuclear cardiology.

And if you buy BOTH "Preparation" and the "Review," you'll save $5.00 off the "Preparation" cover price.

It's easy to order. Simply call the SNM's distributor, Matthews Medical Books, at their toll-free number–

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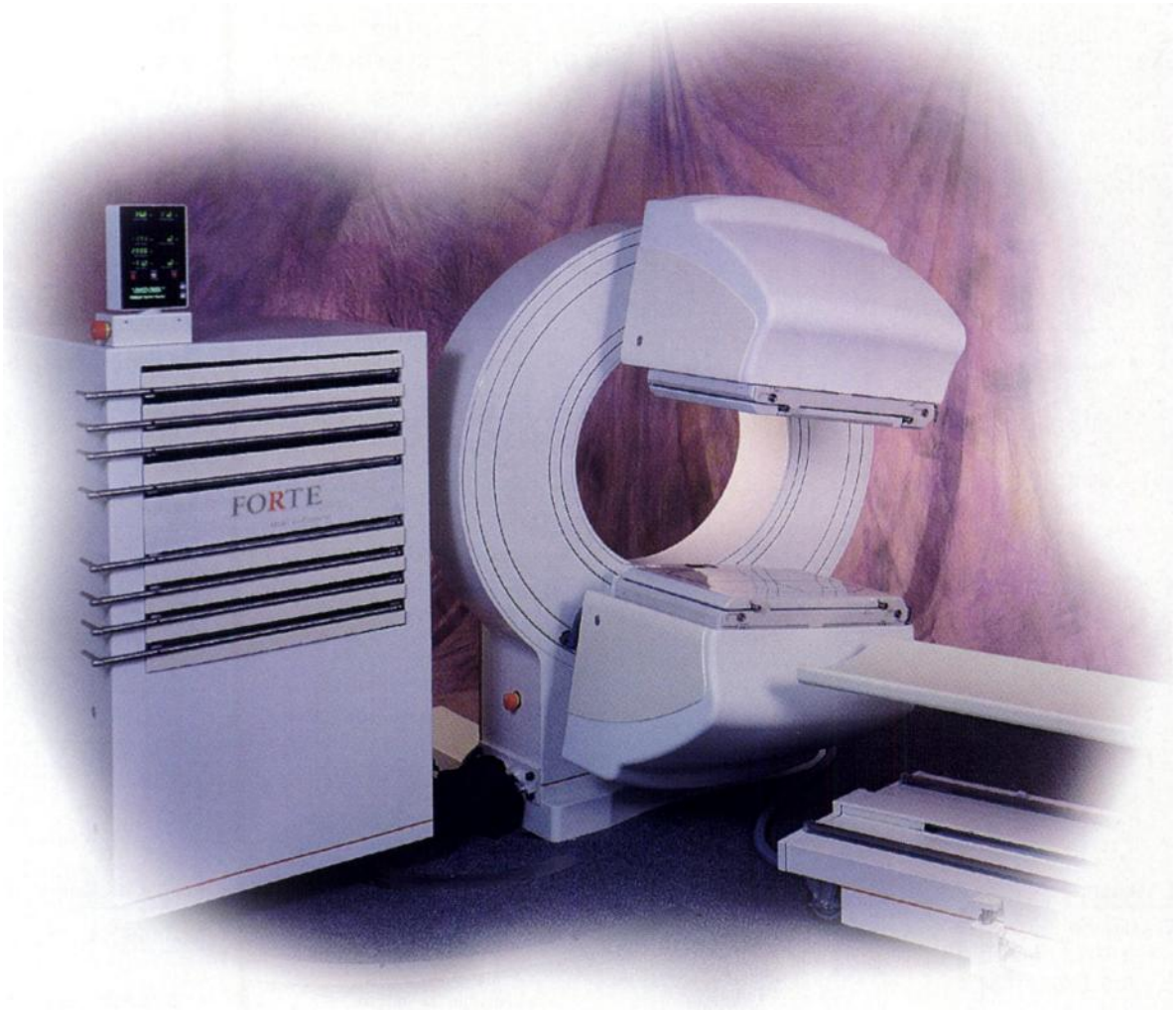
Leadership in nuclear medicine...

It's our Forte™.



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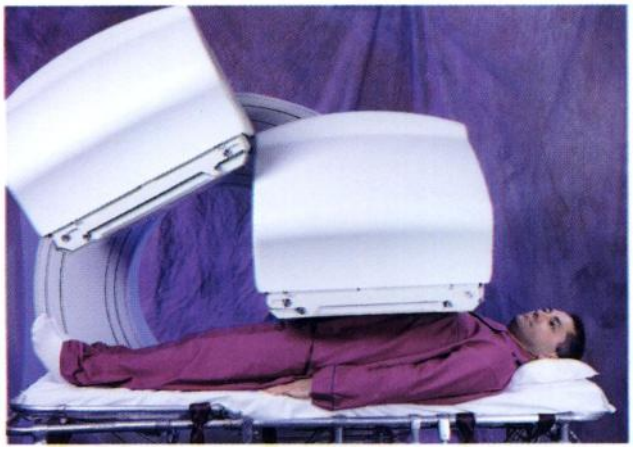
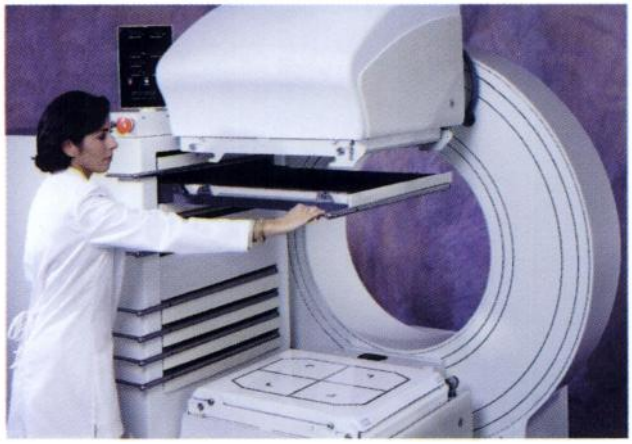


CLINICAL VERSATILITY

- With Forte, patients may be scanned on gurneys, hospital beds, and wheel chairs without obstruction from detector arms or gantry feet.
- The Forte's unique EZX detector position allows the user to image the entire body of a patient on a gurney.
- The Forte's unique design makes it possible to image the abdomen, chest, and pelvis with your patient's head comfortably outside of the gantry.



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- The new ColliMATE automatic system allows effortless collimator exchange in under three minutes.
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- FreeDOME gantry, ADAC's newest innovation, is designed for full patient accessibility with maximum stability.
- Our patented Direct Mount Dual Ring technology provides a precise center of rotation while eliminating gravitational sag.
- The Forte imaging system includes today's fastest computer platform: the new Pegasys™ Ultra 60.
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