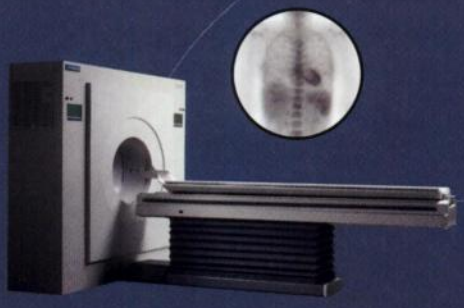
SIEMENS



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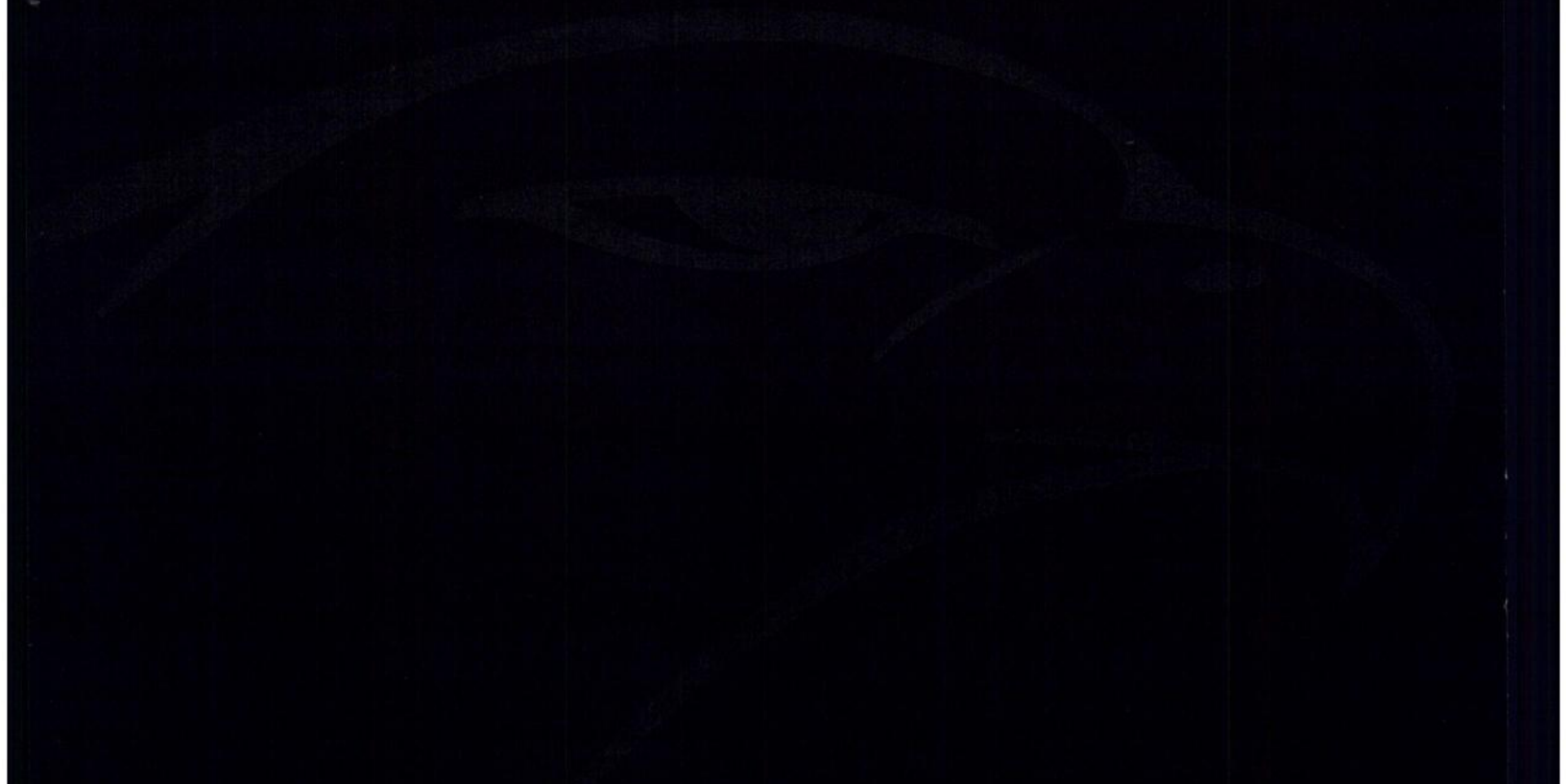

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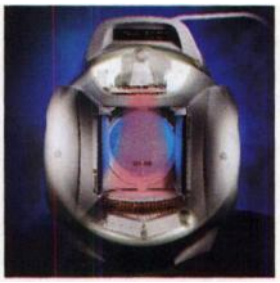

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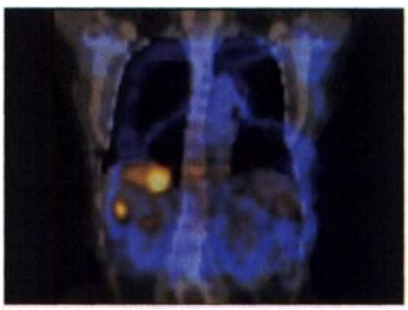

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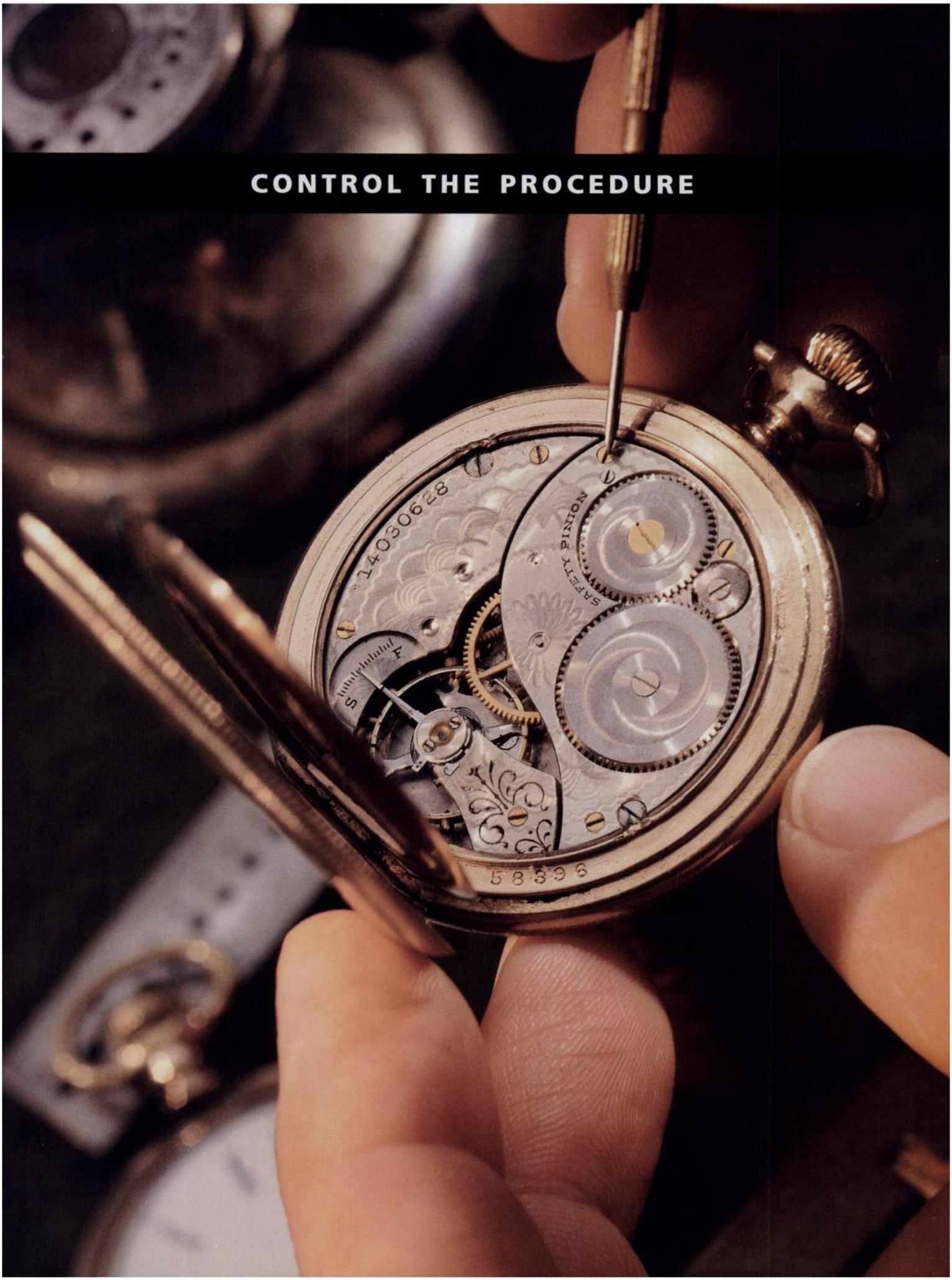
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Precisely.

During SPECT imaging with pharmacologic stress, you don't want any surprises from your vasodilator.

Adenoscan—clockwork precision.

Its rapid action and ultra-short half-life (<10 sec.) mean that you're in control of your procedure. In general, Adenoscan's effects are well tolerated and spontaneously resolve after infusion.

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ADENOSCAN®
adenosine injection

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Intravenous Adenoscan® (adenosine injection) is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

Side effects that were seen most often included flushing (44%), chest discomfort (40%), and dyspnea (28%). Side effects are seldom serious, usually resolve quickly when infusion is terminated, and generally do not interfere with test results.

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.

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

 AS763 7/00

BRIEF SUMMARY

ADENOSCAN®

adenosine injection

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 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. Appropriate resuscitative measures should be available.

Sinoatrial and Atrioventricular Nodal Block

Adenoscan 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 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 diseases, 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 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 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 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.

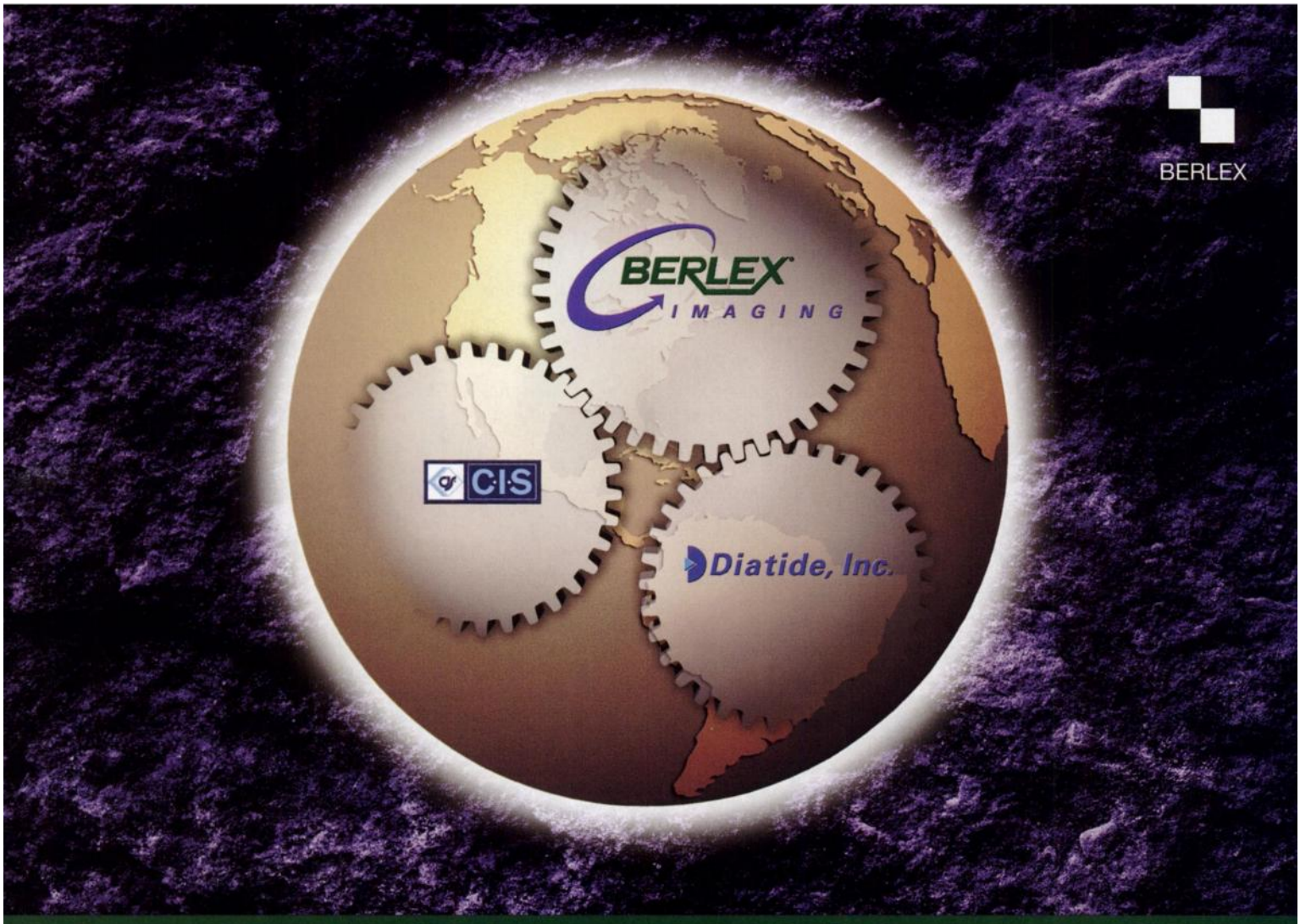
The safety and efficacy of Adenoscan administered by the intracoronary route have not been established.

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

Rx only

Fujisawa Healthcare, Inc.
Deerfield, IL 60015

47001/Revised: April 2000



Partnering for the Advancement of Nuclear Medicine

As a specialist in nuclear medicine, you understand the value that partnering can bring to your patients. Combining your knowledge and experience with the right equipment, products, and supplies, you create a synergy of elements that offers the best chance for successful diagnosis and treatment.

Synergy for Better Patient Care

Berlex Imaging understands your drive to enhance diagnostic and therapeutic performance to deliver your patients the highest level of care. Sharing these same goals, Berlex Imaging has recently created an alliance to raise the level of excellence in nuclear medicine imaging and therapy. Each partner brings a variety of strengths to this alliance:

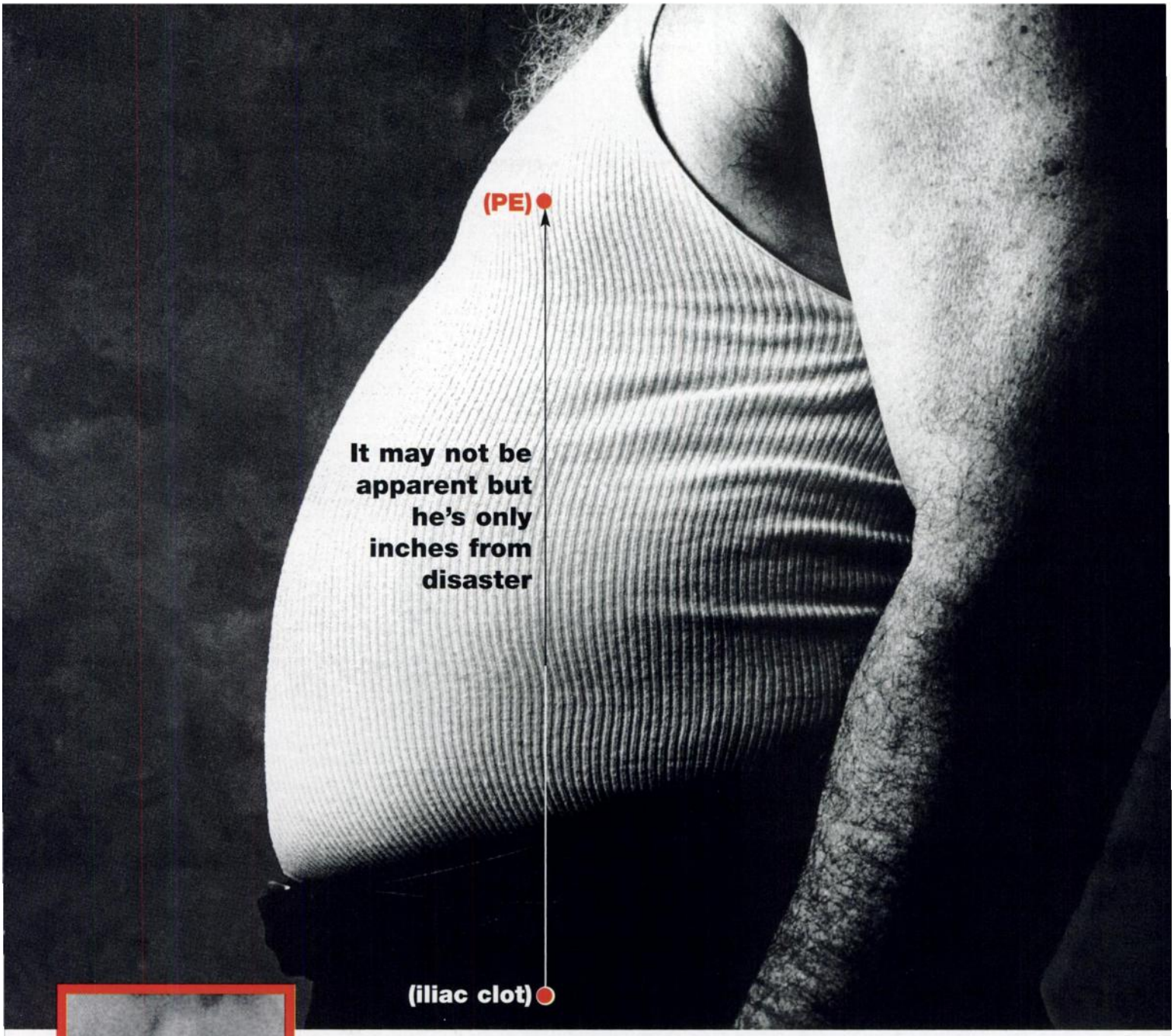
- **Berlex Imaging** introduced the first MRI intravenous contrast agent and is the undisputed market leader. Central to the philosophy at Berlex Imaging is personal involvement in the fields it serves, as evidenced by its outstanding record of continuing education and customer service programs.
- **Diatide** has pioneered innovative peptide engineering and technetium radiolabeling chemistry, producing "smart drug" technology to "find-fight-follow"™ disease.
- **CIS-US** is a leading supplier of traditional radiopharmaceuticals for the diagnosis and treatment of tumor pathologies and diseases of major organ systems.

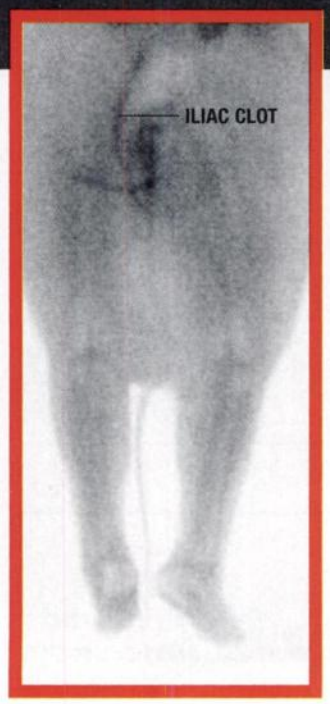
Furthering Our Commitment to Nuclear Medicine

This new alliance, under the Berlex Imaging name, is committed to continued advancements in nuclear medicine diagnostics and therapies. Berlex Imaging is dedicated to bringing you "everything you need to see," from radiology to nuclear medicine, and beyond.

BERLEX® IMAGING

Everything you need to see





AcuTect offers a greater measure of confidence, especially in difficult, time-consuming cases of suspected Deep Vein Thrombosis.

As the first imaging modality to target acute DVT, AcuTect increases your ability to detect dangerous clots in patients with signs and symptoms. AcuTect represents an option for increased confidence — particularly vs. ultrasound — when you're faced with difficult patient types, such as the obese, or those with deep iliac clots, immobility, casts, or other constraints. AcuTect finds its target, binding preferentially to the glycoprotein (GP) IIb/IIIa receptors found on activated platelets.[1,2] And that means rapid and specific detection of acute DVT — with greater throughput.

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

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

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

Please see brief summary of prescribing information on back.

The difference is acute.

BERLEX

For more information call 1-877-342-8433 or visit our Web site, www.AcuTect.com

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ACUTECT

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

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please consult Full Product Information before using.

DESCRIPTION

AcuTect™, Kit for the Preparation of Technetium Tc 99m Apcitide Injection, is intended for use in the preparation of technetium Tc 99m apcitide, a diagnostic radiopharmaceutical to be used by intravenous injection. Each vial contains a sterile, nonpyrogenic lyophilized mixture which is formulated with 100 µg of 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
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References: 1. AcuTect Prescribing Information. 2. Becker RC. Antiplatelet therapy. *Science & Medicine.* July/August 1996:12-21.

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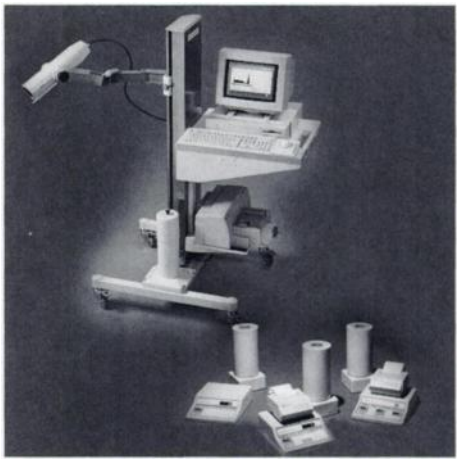

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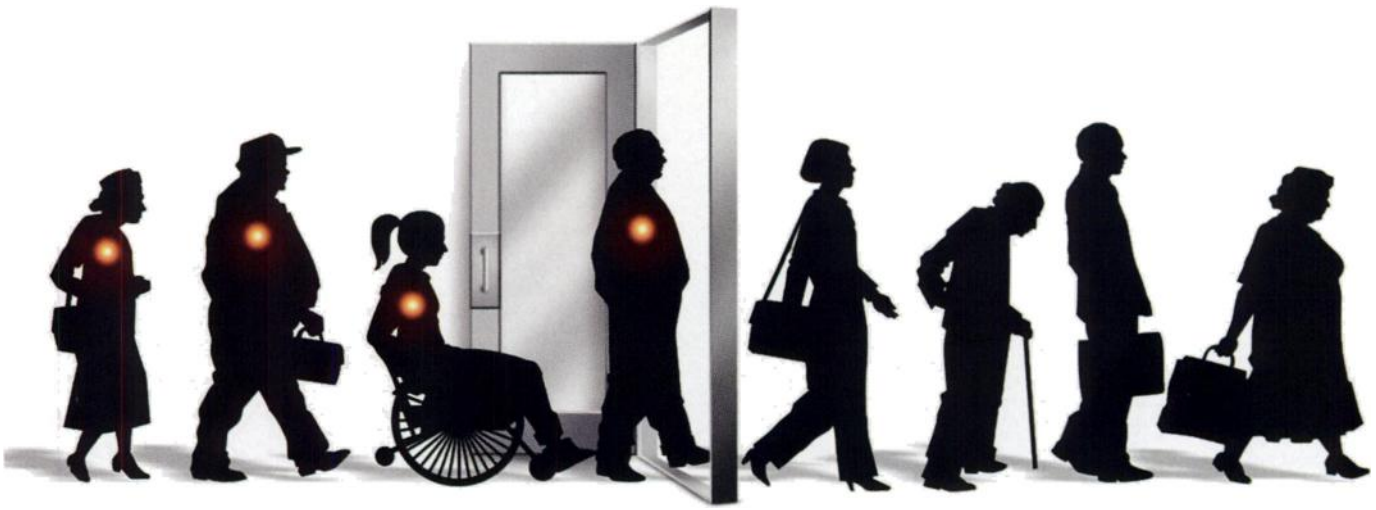

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In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.

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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Kit for the Preparation of Technetium Tc99m Tetrofosmin for Injection
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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 8.61×10^{-3} mSV/MBq and 1.12×10^{-2} mSV/MBq after exercise and rest, respectively.

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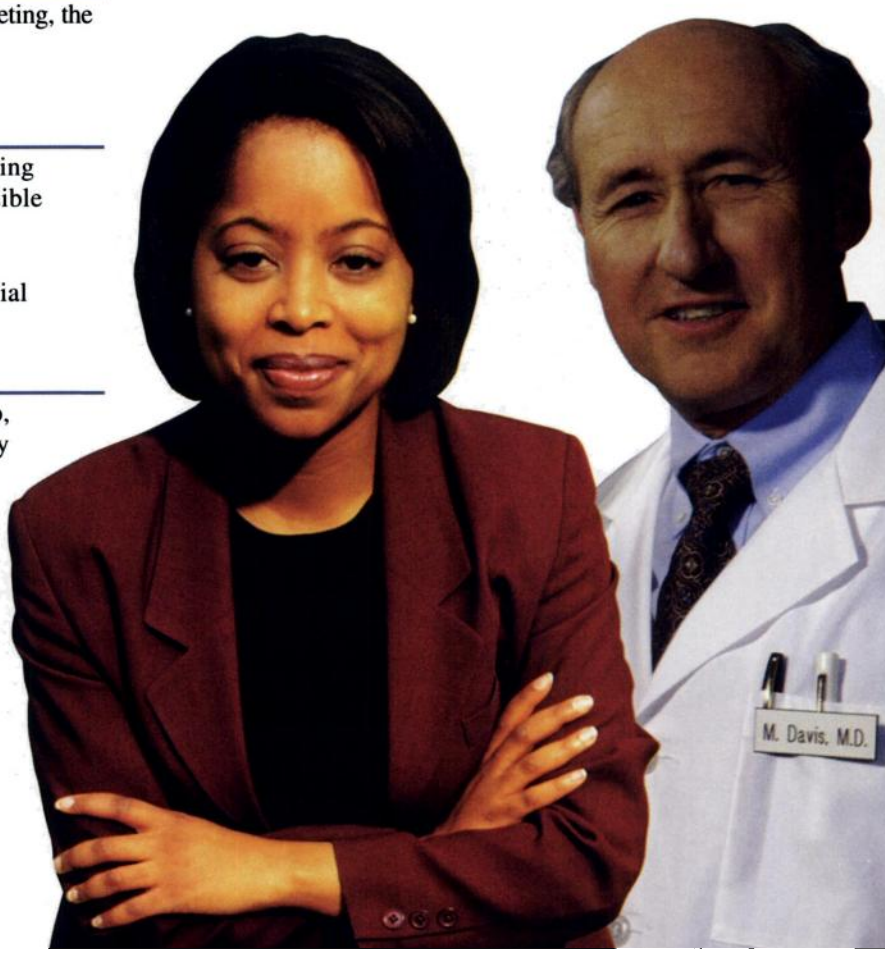

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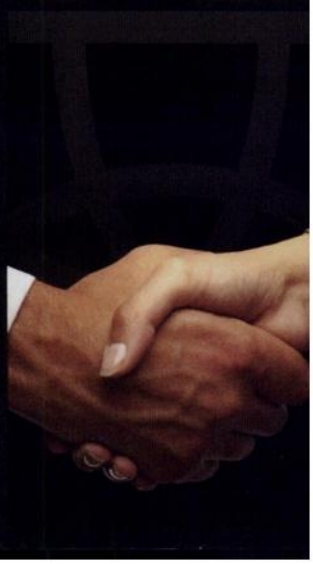

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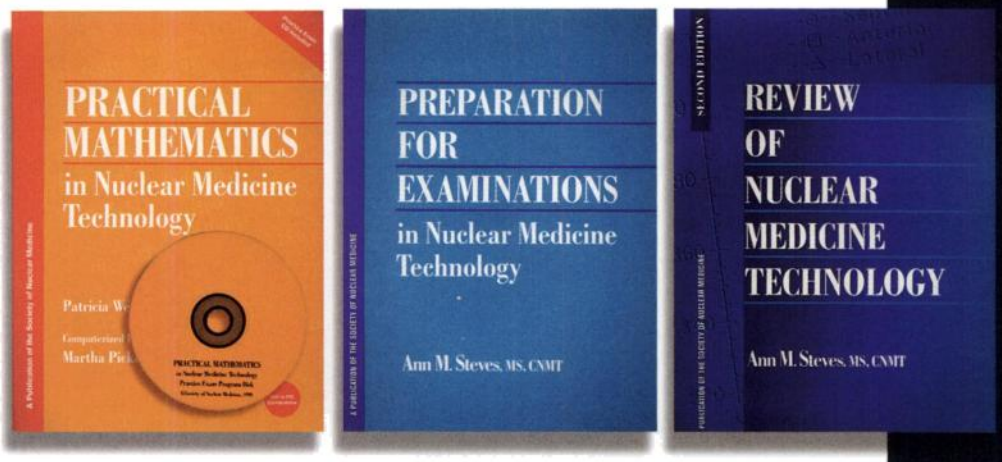

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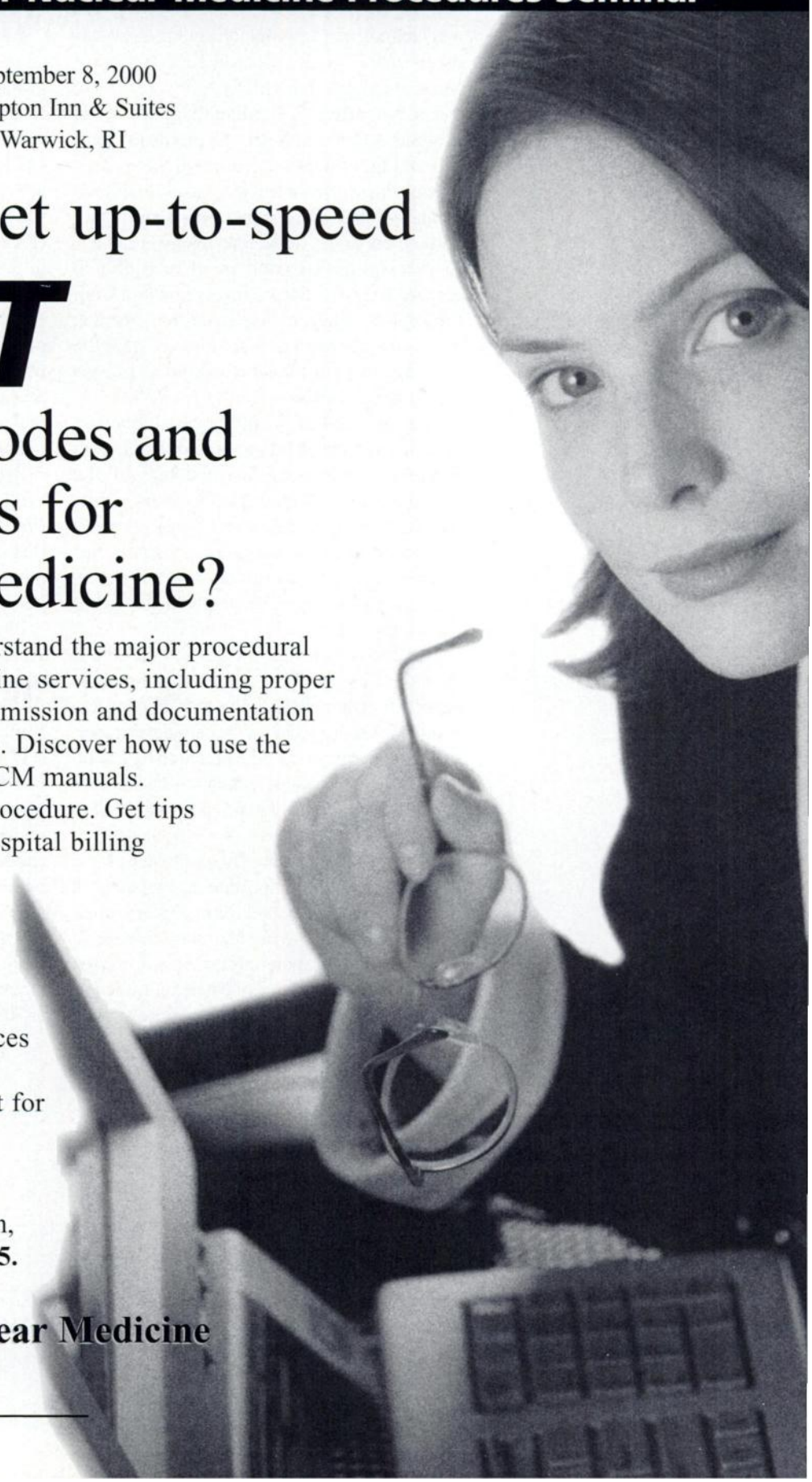

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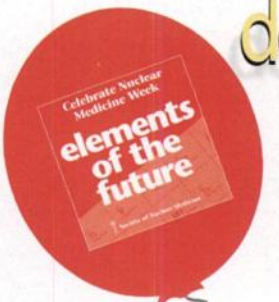

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Nuclear Imaging–Pittsburgh, PA
ABR-Certified Radiologist with ABMN Certification or ABR special competence in Nuclear Radiology sought for busy private practice at university affiliated hospital. Experience in nuclear cardiology a must. Capabilities in cross-sectional imaging and general radiology also required. Immediate availability. Please submit cover letter, CV and references to: C.R. Jarmolowski, MD, Department of Radiology, UPMC Shadyside Hospital, 5230 Centre Avenue, Pittsburgh, PA 15232.

Nuclear Medicine Tech
The Medical Center of Central Georgia is recognized nationally as a "Top 100 Hospital" in the country. We offer a competitive salary and benefits package. We are currently seeking a Nuclear Medicine Tech to work at our Central GA Diagnostic facility. Must be a graduate of an AMA approved School of Radiologic Technology or a BS in Nuclear Medicine and registered or eligible through the ARRT or NMTB. Days. Please send resume to: Bea Ross, The Medical Center of Central GA, PO Box 6000, Hospital Box 132, Macon, GA 31208. Fax: (912) 633-7674. Email: ross.beatrice@mccg.org.

Nuclear Medicine Faculty Position
The Department of Radiology of the University of Michigan Medical School and the Department of Veterans Affairs Health System has an open position for a physician to join the Nuclear Medicine faculty. The position is junior faculty, full-time and non-tenure, in the clinical track, based at the Veterans Affairs Medical Center in Ann Arbor, Michigan. Responsibilities include clinical nuclear medicine practice, participation in a regional telenuclear medicine network and instruction of both medical students and residents. The candidate will be encouraged to take part in the wide range of research opportunities. Qualified candidates must be certified by the American Board of Nuclear Medicine or an equivalent board. Applicants must be competent not only in general radionuclide imaging, but also in cardiac nuclear medicine, including stress testing, diagnosis and treatment of thyroid diseases, thyroid cancer and other radionuclide therapies. The Nuclear Medicine Service at the Veterans Affairs Medical Center in Ann Arbor has state-of-the-art imaging capabilities housed within a completely new modern facility. Interested applicants should contact Donna Eder, Manager, Human Resources, Department of Radiology, UH B1F510/0030, University of Michigan Medical Center, 1500 E. Medical Center Drive, Ann Arbor, MI 48109-0030. The University of Michigan and the Department of Veterans Affairs are Equal Opportunity Employers.

Nuclear Med Tech
Come join the dynamic team at our 200 bed acute care facility. We enjoy an outstanding reputation for quality reaching far beyond our local area. CHRISTUS St. Patrick Hospital is seeking a Nuclear Medicine Technologist for our Radiology Department. Responsibilities include performing nuclear medicine and nuclear cardiology procedures. You will be on call a minimum of 11 days per month. New graduates encouraged to apply. Complete benefit package includes immediate medical insurance coverage, vision, free use of fitness center, employer paid retirement program, sign-on bonus, relocation assistance and much more. Jo Anderson, Recruiter, P.O. Box 3401, Lake Charles, LA 70601. Phone: (337) 491-7572. Fax: (337) 491-7769. E-mail: jo_anderson @sph.christushealth.org.

Director of Nuclear Cardiology/ PET Medicine

Buffalo Cardiology & Pulmonary Associates, P.C., a busy practice located in Western New York, is currently seeking a board certified cardiologist to serve as Director of Nuclear Cardiology/PET Medicine. Candidates must have experience (or be willing to train) in PET technology, administration of day-to-day operations, directing research, and a strong interest in cardiac PET applications. Nuclear license required. Excellent opportunity with partnership potential.

Please send CV to:
Samuel Iacuzzo
Human Resources Department
Buffalo Cardiology
& Pulmonary Associates, P.C.
5305 Main Street
Williamsville, NY 14221
Fax: (716) 565-6678

Staff Physician and Staff Scientist Position
Molecular Imaging Branch
National Institute of Mental Health

The National Institute of Mental Health (NIMH) has established a new Molecular Imaging Branch to expand PET radiotracer development, with imaging applications in both humans and animals. Staff Scientist (PhD) and Staff Physician (MD) positions are available for evaluation and application of PET tracer imaging to provide neurochemical information relevant to the pathophysiology and treatment of neuropsychiatric disorders. In addition to traditional membrane-bound receptor targets, this Branch will seek to develop probes for intracellular signal transduction and gene expression. Although not strictly segregated, the PhD Scientist would more likely be involved in imaging studies in animals (both rodent and non-human primates); and the MD Physician with studies in human subjects. Studies in psychiatric populations are strongly encouraged and will be performed in collaboration with other Branches at NIMH. Candidates must have a Ph.D. and/or M.D. with an established record of scientific accomplishments and possess a strong publication record. Start date is flexible but would optimally be within the period Oct. 1, 2000 to July 1, 2001. Applicants should send a curriculum vitae, statement of research interests, and list of six references by **Sept. 15, 2000** to: Robert B. Innis, MD, PhD, Chief, Molecular Imaging Branch; c/o Office of Scientific Director, NIMH; Bldg.10, Rm. 4N222, 10 Center Drive-MSC1381; 9000 Rockville Pike; Bethesda, MD 20892-1381.

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Associate Professor
UCLA School of Medicine

The Department of Molecular and Medical Pharmacology of the UCLA School of Medicine has a position open at the level of an Associate Professor with tenure level position for a board certified Nuclear Medicine physician. This individual would be the Director of the Ahmanson Biological Imaging Clinic that contains the conventional Nuclear Medicine and PET services. Nuclear Medicine is a division of the Department of Molecular and Medical Pharmacology. The Ahmanson Clinic has three PET scanners used 50% for research and 50% for clinical service and 7 gamma cameras. The clinical service performs about 3000 PET scans and 15,000 conventional Nuclear Medicine imaging procedures per year. The center also has state-of-the-art computer and information technologies, as well as an academic environment with Nuclear Medicine and Radiology residents, M.D. and Ph.D. post-doctoral fellows and graduate students. The Ahmanson Clinic has both clinical and basic biological research programs. It also provides an educational program for assisting in the start up of clinical PET services in the U.S., Europe and Asia, consisting of both training at UCLA and a web-based virtual program with over-read. Applicants must be experienced in research and clinical applications in PET and conventional Nuclear Medicine, be able to provide leadership to research and clinical service programs, including ability to acquire NIH grant funding. The closing date will be 7/15/2000.

Applications should be sent to:
Dr. Heinrich Schelbert, Professor of Molecular and Medical Pharmacology
UCLA School of Medicine
Box 951735
Los Angeles, CA 90095-1735

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NUCLEAR MEDICINE TECHNOLOGIST

This is a first shift, full-time position for a graduate of an accredited program in Nuclear Medicine Technology. Qualified candidates should be certified or eligible for certification by the Nuclear Medicine Technology Certification Board.

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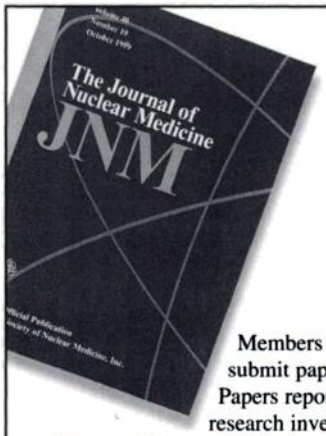

Call for Papers

***The Journal of Nuclear Medicine* (JNM)**

Members and nonmembers are invited to submit papers for publication in the JNM. Papers reporting results from clinical and research investigations of all specialties are welcome. Brief communications detailing preliminary research results in an abridged paper are especially desired. JNM is indexed in *Index Medicus* and on MEDLINE.

Information for authors is available at: www.snm.org/pdf/infoauth_999.pdf

Please forward submissions to:

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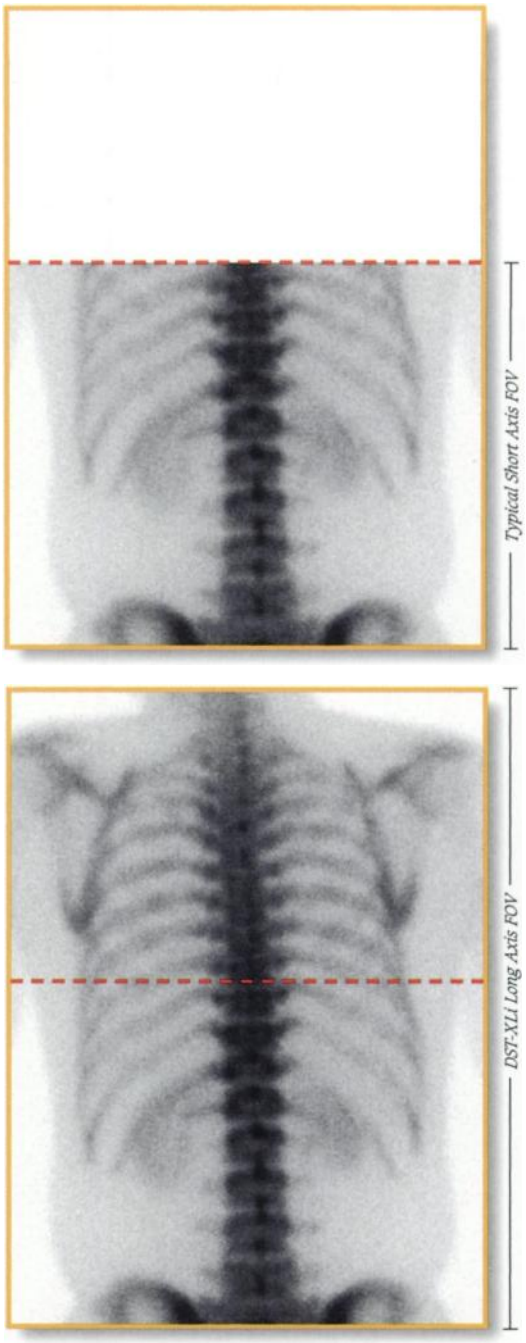

Normal bone scan demonstrating greater long axis coverage and excellent image quality.

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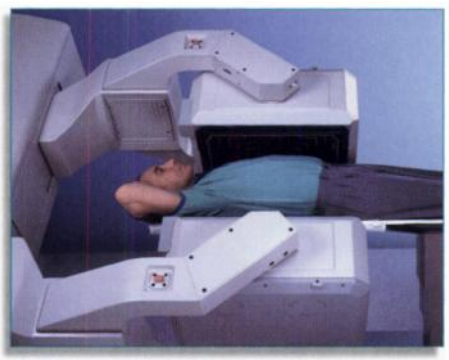

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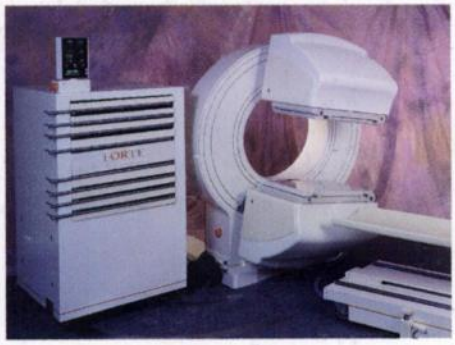

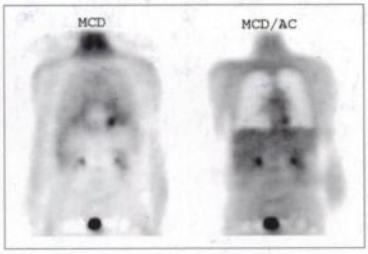

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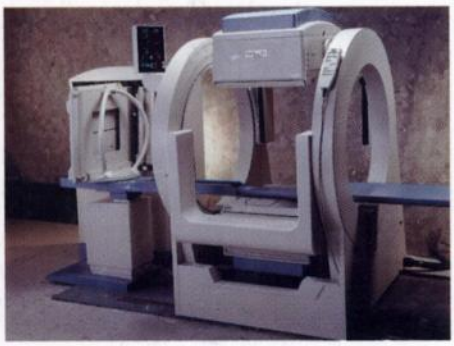


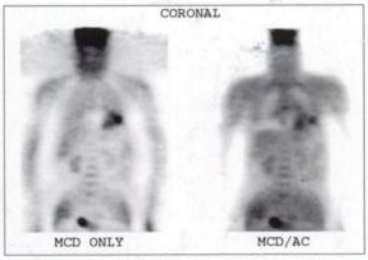
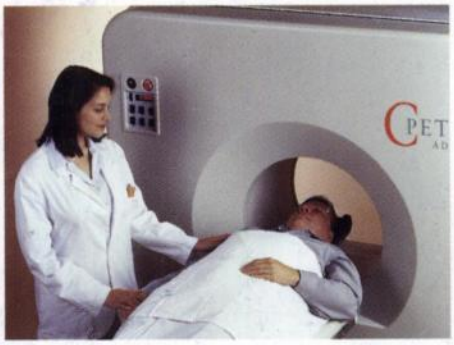
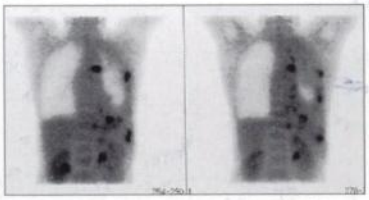


Image courtesy of Dr. Abdel-Dayem, St. Vincents Hospital, NY, NY

C-PET™: Optimized Oncology Imaging





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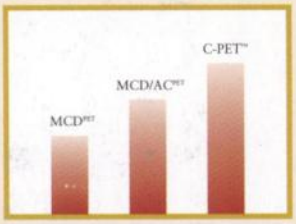

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