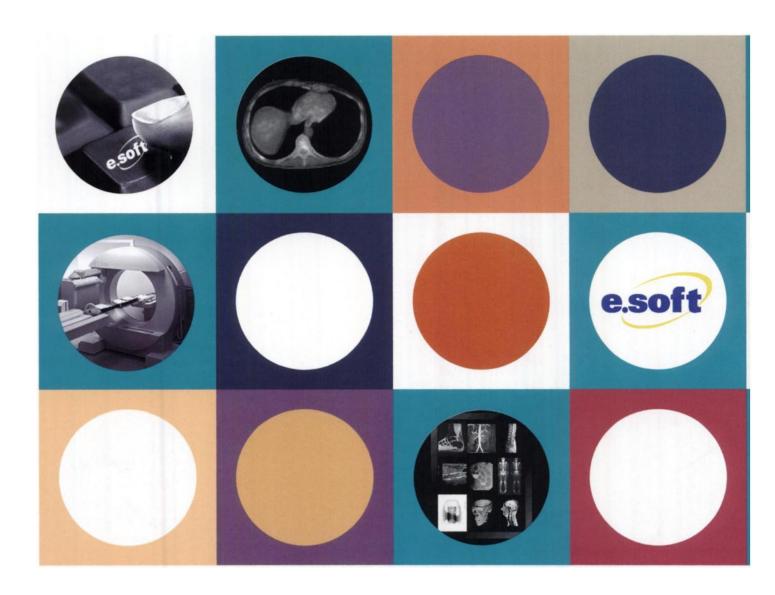
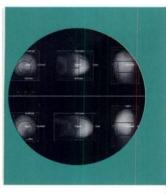
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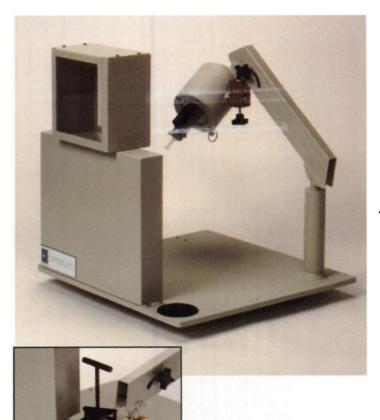




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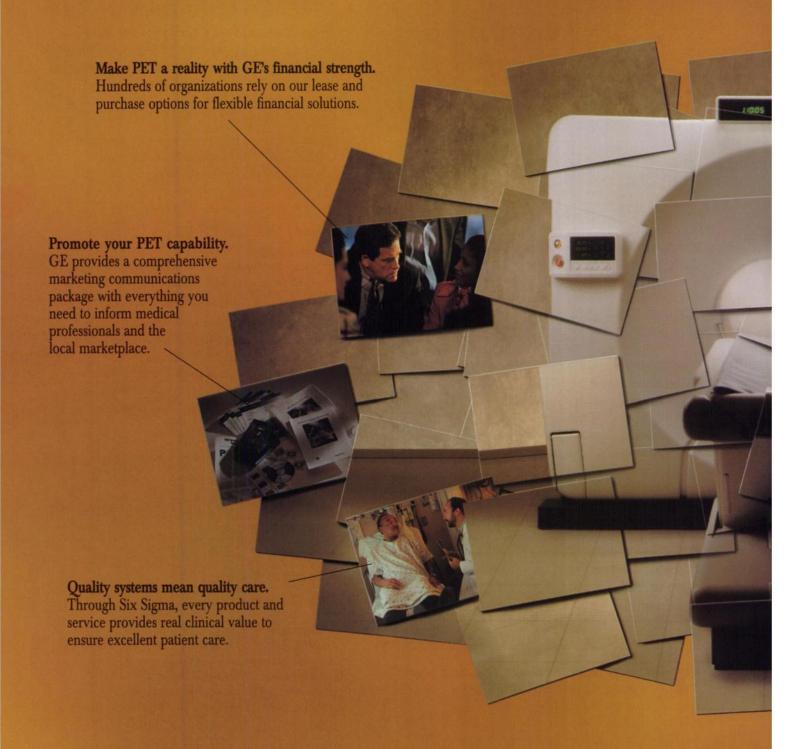
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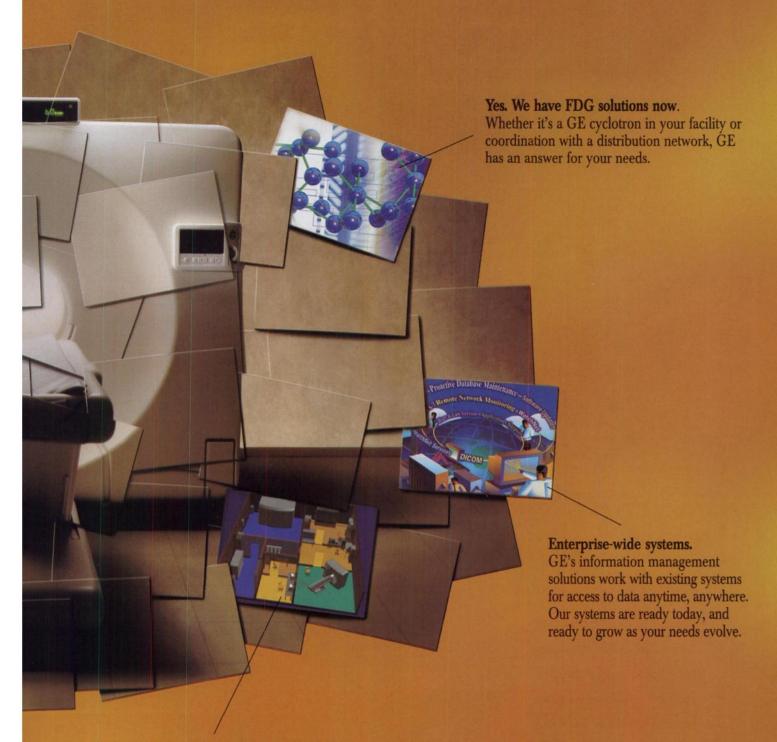
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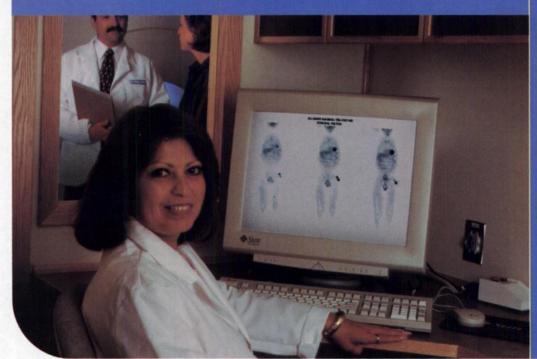
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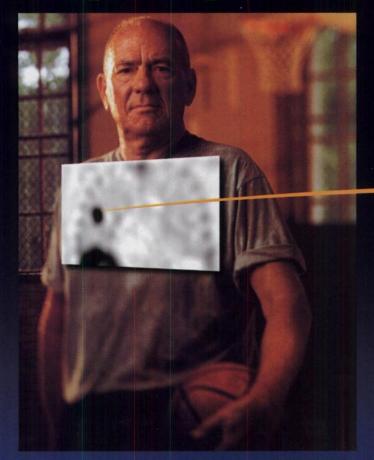
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BOUND TO SEE MORE

Noninvasively Characterizes Pulmonary Masses

NeoTect, a noninvasive nuclear imaging agent, characterizes pulmonary masses as being rich in somatostatin receptors.^{1,2}

- Many malignant pulmonary masses and some inflammatory processes overexpress somatostatin receptors (SSTRs)¹
- For use in patients who are known to have or are highly suspect for malignancy and have pulmonary lesions on CT and/or chest x-ray.¹

The clinical benefit of NeoTect as a population-based screening tool has not been studied. NeoTect is not an alternative to CT or biopsy.¹

NeoTect, like other small peptides, may induce hypersensitivity reactions or anaphylactic reactions. Adequate treatment provisions, including epinephrine, should be available for immediate use.



Normal SPECT image



Positive SPECT image, malignancy confirmed by histology (adenocarcinoma)

Please see brief summary of prescribing information on following page





Brief Summary of Prescribing Information

DESCRIPTION

NeoTect™ (Kit for the Preparation of Technetium Tc 99m Depreotide Injection) is intended for use in the preparation of Technetium Tc 99m Depreotide, a diagnostic radiopharmaceutical to be used by intravenous injection. Each vial contains a sterile, non-pyrogenic lyophilized mixture of 50 µg of Depreotide, 5 mg of sodium glucoheptonate dihydrate, 50 µg of stannous chloride dihydrate (with a minimum stannous tin content of 15 µg), 100 µg eletate disodium dihydrate, and sufficient sodiu hydroxide or hydrochloric acid for adjustment to pH 7.4 prior to hyophilization. The hyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

When sterile, non-pyrogenic Sodium Pertechnetate Tc 99m Injection, in 0.9% Sodium Chloride Injection, U.S.P., is added to the vial, a Technetium Tc 99m complex of Depreotide is formed.

INDICATIONS AND USAGE

 $NeoTect^{TM}$ is a scintigraphic imaging agent that identifies somatostatin receptor-bearing pulmonary masses in patients presenting with pulmonary lesions on computed tomography and/or chest x-ray who have known malignancy or who are highly suspect for malignancy.

CONTRAINDICATIONS

None know

WARNINGS

None.

PRECAUTIONS

Therapy with somatostatin analogues can produce severe hypoglycemia in patients with insulinomas. Since Decreotide binds to sometostatin receptors, caution should be exercised when administering this drug to patients with insulinomas.

NeoTect™, as other small peptides, may induce hypersensitivity reactions or anaphylactic reactions. Adequate treatment provisions, including epinephrine, should be available for immediate use. In preliminary studies of 18 subjects. NeoTect™ did not produce increases in IgG or IgM production 3 weeks following injection. Other immune parameters such as eosinophils, other munoglobulins, complement, lymphokines or cytokines were not studied.

Technetium Tc 99m Depreotide 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.

Urinary excretion of radioactivity occurs primarily during the first 4 hours following injection. Studies have not been done to determine the amount of radioactivity that might be eliminated in the feces. (See Clinical Pharmacology Section.) Special precautions should be taken with incontinent patients to minimize the risk of radioactive contamination of clothing, bed linen, and the patient's environment

ntion For Patients

To minimize radiation absorbed dose to the bladder, adequate hydration should be encouraged to permit frequent voiding during the first few hours after injection of NeoTect™. This may be achieved by having patients drink at least an 8 oz. glass of water prior to drug administration. To help protect themselves and others in their environment, patients should take the following precautions for 12 hours after injection: whenever possible a toilet should be used and should be flushed several times after each use and patients should wash their hands thoroughly after each voiding or fecal elimination. If blood, urine or feces soil the clothing, the clothing should be washed separately aboratory Tests

There was a low incidence (1% or less) of transient and clinically insignificant changes in alanine aminotransferase (ALT), white blood cell count, and eosinophil count following administration of Technetium Tc 99m Depreotide Injection.

Drug Interaction

Drug interactions were not noted in clinical studies in which Technetium Tc 99m Depreotide Injection was administered to patients receiving concomitant medication.

esis, Mutage nesis, Impairment of Fertility

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. The results of the following genotoxicity studies with decayed Technetium Tc 99m Depreotide Injection or with deprectide were negative: Salmonella/Escherichia coli reverse mutation assay, in vitro mouse lymphoma assay with and without metabolic activation, and in vivo mouse

Pregnancy Category C. Animal reproduction studies have not been conducted with decayed Technetium Tc 99m Deprectide Injection. It is not known whether Technetium Tc 99m Deprectid Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Deprectide Injection should be given to a pregnant woman only if clearly needed. Studies in pregnant women have not been conducted.

Studies have not been conducted with depreotide to determine its excretion in human milk. Technetium Tc 99m Pertechnetate is excreted in human milk. It is not known whether Technetium To 99m Depreotide Injection is excreted in human milk. Caution should be exercised when Technetium Tc 99m Depreotide Injection is administered to a nursing woman. Wherever possible, infant formula should be substituted for breast milk until the technetium has been eliminated. Pediatric Use

Safety and effectiveness of Deprectide in pediatric patients below the age of 16 years have not

ADVERSE REACTIONS

Adverse events were evaluated in clinical studies of 647 adults who received 15.0 to 20.0 mCi Technetium Tc 99m labeled to approximately 50 µg of depreotide. Of these adults, 58% were men and 42% women. The mean age was 59.0 years (18-86 years).

Deaths did not occur during the clinical study period. After Technetium Tc 99m Depreotide Injection, serious adverse events were not reported.

At least one adverse event occurred in 29/647 (4.5 %) patients after Technetium Tc 99m Depreotide Injection. Headache was the most commonly reported adverse event (1% of patients). Table 8 lists adverse events reported in 0.5% or more of patients who received Technetium Tc 99m Depreotide

TABLE 8 ADVERSE EVENTS REPORTED IN ≥ 0.5% OF PATIENTS FOLLOWING NeoTect™ INJECTION IN CLINICAL TRIALS		
Number of Patients Exposed	647	
Number of Patients with At Least One Adverse Event	29 (4.5%)	
Nervous System	13 (2%)	
Headache	7 (1.0%)	
Dizziness	5 (0.8%)	
Gastrointestinal System	7 (1.0%)	
Nausea	4 (0.6%)	
Vascular (extracardiac) Disorder	3 (0.5%)	
Flushing	3 (0.5%)	

Other adverse events which occurred in < 0.5% of patients following administration of NeoTect™ included: arthrosis, back pain, chest pain, diarrhea, fatigue, gait abnormality, glossitis, hemoptysis, hypoaesthesia, infection, leg cramps, lymphocytosis, malaise, pharyngitis, so

DOSAGE AND ADMINISTRATION

For imaging, NeoTect™ is administered as a peripheral intravenous injection at a single dose of 15 to 20 mCi containing approximately 50 µg of Technetium Tc 99m radiolabeled Depreotide peptide. Patients should drink at least an 8 oz. glass of water before drug administration.
The contents of Kit for the Preparation of Technetium Tc 99m Depreotide Injection are intended only

for use in the preparation of Technetium Tc 99m Depreotide Injection and are not to be administered directly to the patient. Only one patient dose should be drawn from each reconstituted vial. (See Instructions for the Preparation Section.)

The potential need for dose adjustment has not been studied in patients with renal insufficiency, or in pediatric or geriatric patients, or in patients on therapeutic somatostatin analogues.

IMAGING

Planar and SPECT images of the chest should be obtained between 2-4 hours after NeoTect™ administration. SPECT images of the chest are required for optimal image interpretation.

RADIATION DOSIMETRY

Based on human data, the absorbed radiation dose to an average human adult (70 kg) from an intravenous injection of the agent are listed in Table 9. The values are listed in descending order as rad/mCi and mGy/MBq and assume urinary bladder emptying at 4.8 hours.

Table 9 Estimated Absorbed Radiation Dose			
Target Organ	rad/mCi	mGy/MBq	
Kidneys	0.33	0.090	
Spleen	0.16	0.042	
Testes	0.11	0.031	
Thyroid Gland	0.088	0.024	
Red Marrow	0.078	0.021	
Liver	0.078	0.021	
Heart wall	0.054	0.014	
Bone surface	0.054	0.015	
Lungs	0.053	0.014	
Adrenal glands	0.044	0.012	
Pancreas	0.037	0.010	
Urinary bladder	0.033	0.0089	
Uterus	0.031	0.0084	
Small Intestine	0.019	0.0050	
Upper Large Intestine	0.019	0.0050	
Ovaries	0.016	0.0042	
Lower Large Intestine	0.014	0.0038	

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 0.023 mSv/MBq (0.084 rem/mCi).

HOW SUPPLIED

Each kit is comprised of one vial containing a sterile, non-pyrogenic, freeze-dried mixture of Depreotide, stannous chloride dihydrate, sodium glucoheptonate dihydrate and edetate disodium dihydrate. Kits are available as individual vials or as packs of five

MDC 64570-511-10 - single vial NDC 64570-511-05 - five vial pack

STORAGE

Store the kit at ≤ -10° C (≤ 14° F). Store the reconstituted injection solution at 20-25° C (68-77° F) using appropriate radiation shielding. Use within 5 hours of reconstitution. The kit should be protected from light.

Rx Only

Diatide, Inc.

9 Delta Drive

Londonderry, New Hampshire 03053

Revised August 1999

References: 1. NeoTect™ Prescribing Information. 2. Blum JE, Handmaker H, Rinne NA. The utility of a somatostatin-type receptor binding peptide radiopharmaceutical (P829) in the evaluation of solitary pulmonary nodules. Chest. 1999;115:224-232.

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

DESCRIPTION

AcuTectTM, 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 Ivophilization. The Ivophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product does not contain an antimicrobial preservative.

Bibaccitide is composed of two accitide monomers. When sterile, nonovrogenic 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^M is indicated for scintigraphic imaging of acute venous thrombosis in the mities 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

The contents of AcuTect^M 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 me 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.

on for Pati

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. petients 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 applitude 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/Illa receptors on activated platelets was not studied. The effect of the duration of anticoaculation on accitide 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 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.

sing Met

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.

intric Line

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 Acuted™ INJECTION IN CLINICAL STUDIE		
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 AcuTectTM 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 applitude 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 approximate 100 ug of bibaccitide 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.)

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	0.0053/0.006	
Lungs	0.016	0.6043	
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.

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

Rev. September 1998 9 Delta Drive, Londonderry, New Hampshire 03053 Distributed by: Diatide, Inc. and Nycomed Amersham 60-801980-A

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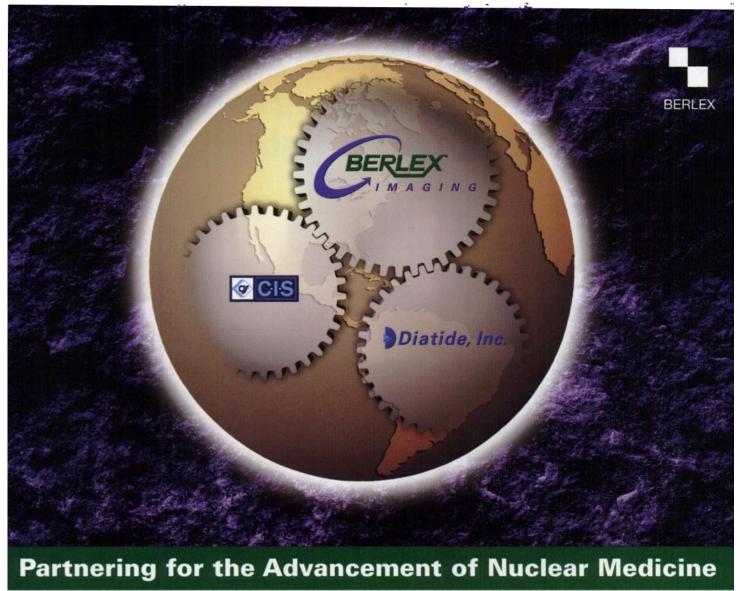
References: 1. AcuTect Prescribing Information. 2. Becker RC. Antiplatelet therapy. Science & Medicine. July/August 1996:12-21

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- Diatide has pioneered innovative peptide engineering and technetium radiolabeling chemistry, producing "smart drug" technology to "find-fight-follow"™ disease.
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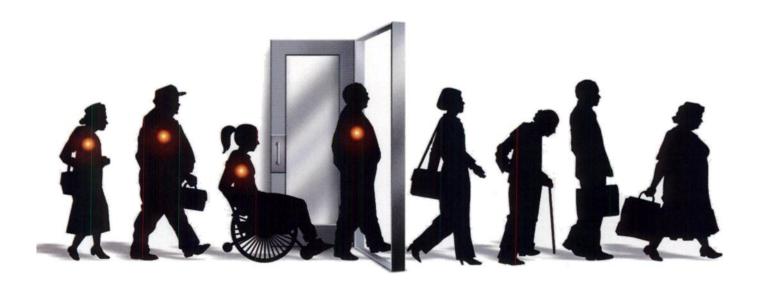
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In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.

Please see Brief Summary of Prescribing Information on adjacent page.

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References: 1. Sridhara BS, Braat S, Rigo P, et al. Comparison of myocardial perfusion imaging with technetium-99m tetrofosmin versus thallium-201 in coronary artery disease. Am J Cardiol. 1993;72(14): 1015-1019. 2. Higley B, Smith FW, Smith TW, Smith T, et al. Technetium-99m-1,2-bis[bis[2-ethoxyethyl]phosphino]ethone: 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 TH

BS-43-1011A

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

R_x ONLY

Please consult full prescribing information before using. A summary

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 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

Genera

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 (5-6 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

Genera

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 tetrolosmin 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

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

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No.1 (rev). Society of Nuclear Medicine, 1976). Effective dose equivalents (EDE) were calculated in accordance with ICRP 53 (Ann. ICRP 18 (1-4),1988) and gave values of 8.61 x 10³ mSV/MBq and 1.12 x 10³ mSV/MBq after exercise and rest,

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Patent No. 5,045,302 (r)

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See your way clear

Decisive information keeps you on course

Guiding you to optimal intervention for neuroendocrine tumors

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

The accepted standard for GEP* tumors

An emerging choice for small cell lung cancer

*Gastroentero-pancreatic neuroendocrine tumors



Please see adjacent page for brief summary of prescribing information.

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Kit for the Preparation of Indium In-111 Pentetreotide

Please see adjacent page for brief summary of prescribing information.



Kit for the Preparation of Indium In-III Pentetreotide

BRIEF SUMMARY OF PRESCRIBING INFORMATION

DESCRIPTION

OctreoScan* is a kit for the preparation of indium In-111 pentetreotide, a diagnostic radio-pharmaceutical. It is a kit consisting of two components:

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

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



INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

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

PRECAUTIONS

General

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy Category C

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

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

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

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

DOSAGE AND ADMINISTRATION

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

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

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

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

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

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

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

Radiation Dosimetry

The estimated radiation doses' to the average adult (70 kg) from intravenous administration of 111 MBq (3 mCi) and 222 MBq (6 mCi) are presented below. These estimates were calculated by Oak Ridge Associated Universities using the data published by Krenning, et al.²

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

	PLANAR		SPECT	
Kidneys	54.16	5.42	108.32	10.83
Liver	12.15	1.22	24.31	2.43
Spleen	73.86	7.39	147.73	14.77
Uterus	6.34	0.63	12.67	1.27
Ovaries	4.89	0.49	9.79	0.98
Testes	2.90	0.29	5.80	0.58
Red Marrow	3.46	0.35	6.91	0.69
Urinary Bladder Wall	30.42	3.04	60.48	6.05
GI Tract				
Stomach Wall	5.67	0.57	11.34	1.13
Small Intestine	4.78	0.48	9.56	0.96
Upper Large Intestine	5.80	0.58	11.59	1.16
Lower Large Intestine	7.73	0.77	15.46	1.55
Adrenals	7.55	0.76	15.11	1.51
Thyroid	7.43	0.74	14.86	1.49
Effective Dose ⁴ Equivalent	13.03	1.30	26.06	2.61

- 1. Values listed include a correction for a maximum of 0.1% indium In-114m radiocontaminant at calibration
- E.P. Krenning, W.H. Bakker, P.P.M. Kooji, W.A.P. Breeman, H.Y.Oei, M. de Jong, J.C. Reubi, T.J. Visser, C. Bruns, D.J. Kwekkeboom, A.E.M. Reijs, P.M. van Hagen, J.W. Koper, and S.W.J. Lamberts, "Somatostatin Receptor Scintigraphy with Indium-111-DTPA-D-Phe-1-Octreotide in Man: Metabolism, Dosimetry and Comparison with Iodine-123-Tyr-3-Octreotide," The Journal of Nuclear Medicine, Vol. 33, No. 5, May 1992, pp. 652-655.
- Assumes 4.6 hour voiding interval and International Commission on Radiological Protection (ICRP) 30 model for the gastrointestinal tract calculations.
- 4. Estimated according to ICRP Publication 53.

HOW SUPPLIED

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

- 1. A 10-mL OctroeScan Reaction Vial which contains a lyophilized mixture of:

 (i) 10 µg pentetreotide [N-(diethylenetriamine-N.N.N',N'-tetracetic acid-N'-acetyl)-D-phenylalanyt-L-hemicystyl-L-phenylalanyt-D-tryptophyl-L-hysyl-L-threomyl-L-hemicystyl-L-threomiol cyclic (2-7) disulfield, (also known as octreotide DTPA),

 (ii) 2.0 mg gentisic acid [2.5-dihydroxybenzoic acid],

 (iii) 4.9 mg trisodium citrate, anhydrous,

 (iv) 0.37 mg citric acid, anhydrous, and

 (v) 10.0 mg inositol.

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

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

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

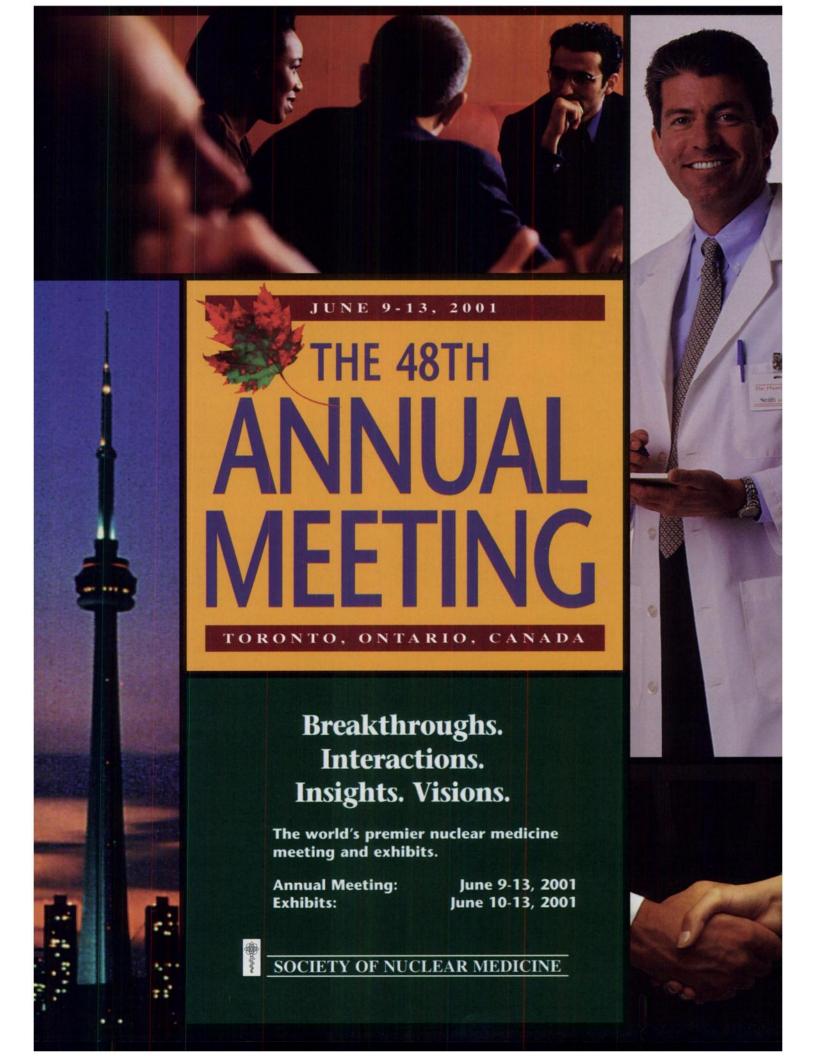


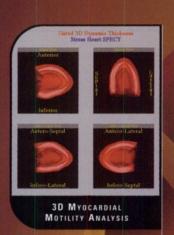
Mallinckrodt Inc. Mallinckrodt Nuclear Medicine Division P.O. Box 5840 St. Louis, MO 63134

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

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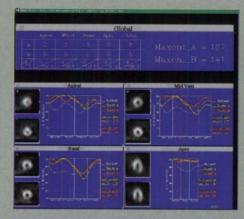
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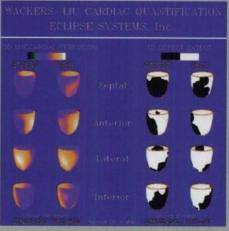
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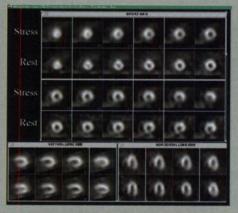
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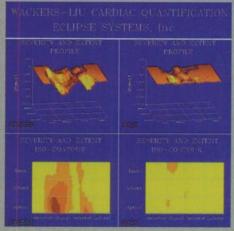
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John G. McAfee, MD Andrew P. Spasoff

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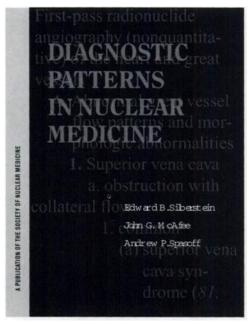


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Part XII: Tumor/Inflammation Imaging (Non-

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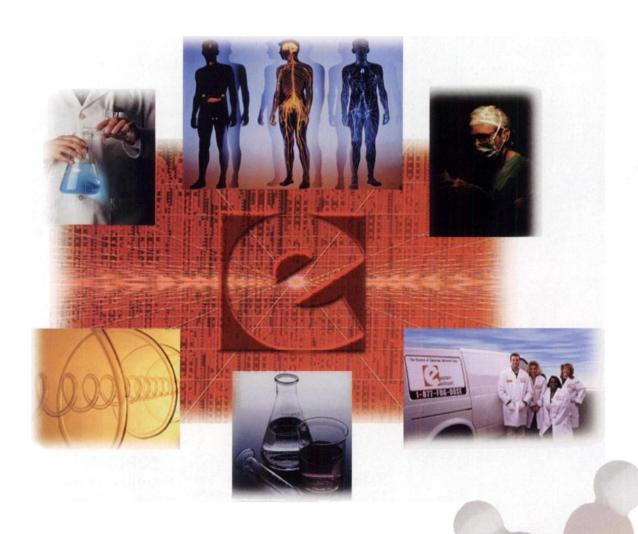
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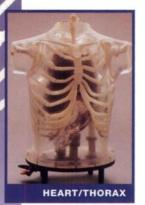
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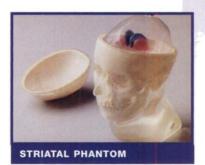


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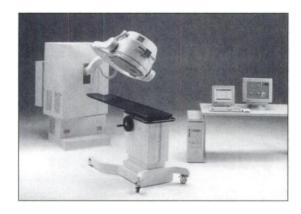
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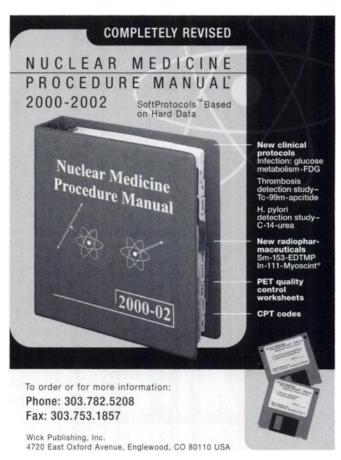
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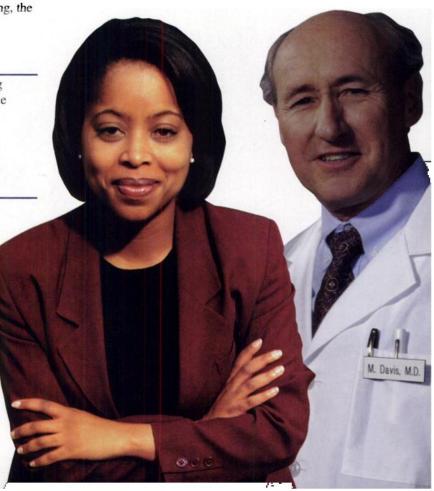
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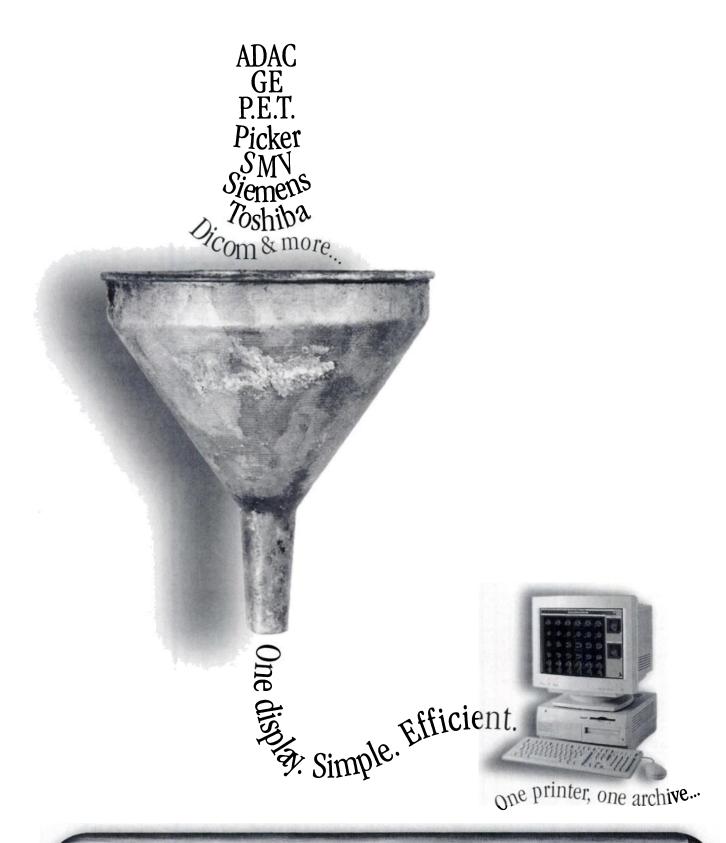
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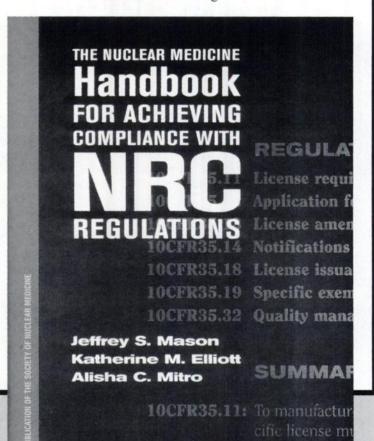
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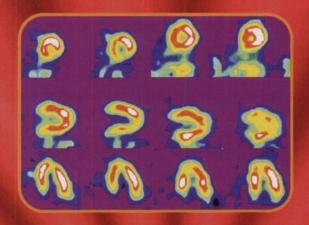
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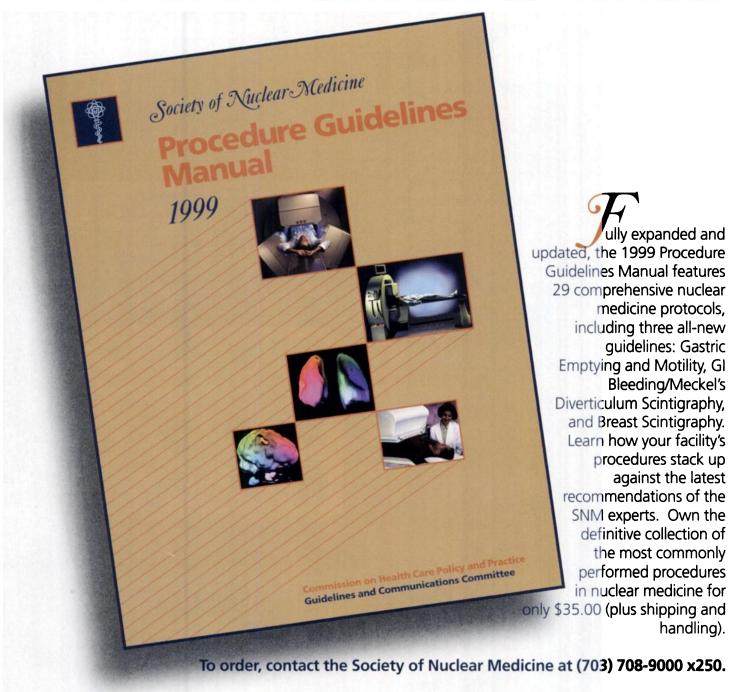
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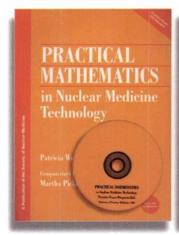
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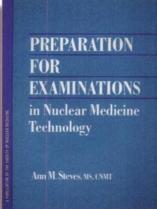
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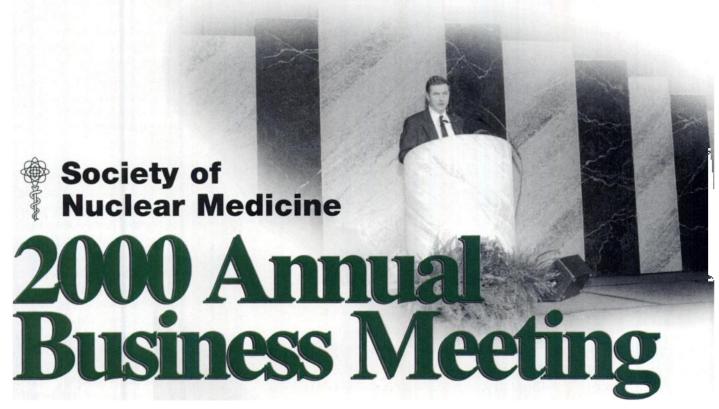
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Robert W. Burt, MD, Director of Nuclear Medicine, Indiana University Hospital, Indianapolis, Indiana.

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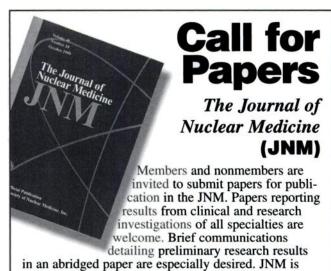
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NeoRx is a publicly traded biotechnology company engaged in the development of radiopharmaceuticals for the treatment of cancer. The Company's lead product, skeletal targeted radiotherapy (STR), is currently completing a Phase II clinical study in multiple myeloma patients, and is expected to enter Phase III trials this year. NeoRx is also developing a series of products to treat cancer based on its Pretarget immunotherapy platform. It is expected that Pretarget products will reach the clinic within the next 12-18 months. We currently have the following opening:

Radiopharmacist/Nuclear Medicine Technologist

Manages the Technical Services department to ensure that radiophar-maceutical products are compounded, dispensed, and administered appropriately in support of STR and future clinical research projects. Responsible for NeoRx pharmacy; leads team to establish and qualify radiopharmacy facilities; and ensures that all functions are in compliance with regulatory and safety requirements. Drafts sections of regulatory documents such as CMC section of an IND or NDA. Able to work under aggressive timelines, while maintaining effective relationships with internal and external personnel, such as contract manufacturers nuclear medicine facilities, and clinical departments. BS degree in chemistry discipline is required (MS preferred), with minimum of 5 years of experience with radiopharmaceuticals or R.Ph., BCNP.

Interested candidates are invited to forward their resume with a cover letter in strict confidence to: Human Resources Dept., NeoRx Corporation, 410 W. Harrison Street, Seattle, WA 98119; Email: jobs@neorx.com. An Equal Opportunity Employer

LA UCLA UCLA UCLA UCLA

Nuclear Medical Technician

UCLA Medical Center, one of the top ten hospitals in America, fosters a pioneering clinical environment, and we offer unequaled challenges and opportunities to further your education, training and career. UCLA has state-of-the-art equipment and we have an exciting opportunity for a Nuclear Medical Technician with at least 3-5 years of experience.

You'll be joining an internationally recognized facility that is responsible for the development of PET and currently the largest PET facility in the nation. We are pioneering imaging modalities for breast cancer in addition to other exciting research. You'll be treating a diverse patient population and we staff a 1:1 staff to camera ratio.

We are seeking someone who enjoys a serious challenge and is very motivated when it comes to adding to their abilities. Rotating call is required. If you feel you are ready to take the next step in challenging your clinical skills, please consider this opportunity. Joining UCLA will give you great benefits, such as medical, dental and vision coverage that start day one, plus substantial reductions on tuition.

Please call/e-mail Jody Erenberg at (310) 794-0506 to discuss this opportunity. E-mail: jerenberg@mednet.ucla.edu. Visit our website at: http://hr.healthcare.ucla.edu for updates on our current positions. FOF

U C L A Healthcare

UCLA UCLA UCLA UCLA UCLA

Nuclear Medicine Faculty Position

The Department of Radiology at The University of lowa College of Medicine has an opening for a Nuclear Medicine physician. This position is full-time, open rank and can be either tenure-track or non-tenure clinical track. One of the largest teaching hospitals in the country, The University of lowa Hospitals and Clinics provides research and clinical facilities—a P.E.T. Center, state-of-the-art nuclear imaging equipment, and extensive image processing capabilities. Applicants must be certified in Nuclear Medicine and preferably in diagnostic radiology. P.E.T. expertise, administrative experience, and strong evidence of scientific productivity including extramurally funded research are desirable. Women and minority candidates are encouraged to apply.

Send resume and cover letter to:

Michael Graham, MD
Professor and Director
The University of Iowa
Department of Radiology, Division Nuclear Medicine
200 Hawkins Drive
Iowa City, IA 52242

The University of Iowa is an Affirmative Action/ Equal Opportunity Employer

PET APPLICATIONS & EDUCATION SPECIALIST

Alliance Imaging, Inc., the leading provider of MRI services in the US is seeking an experienced and professional PET technologist to join its Applications & Education Group. Primary job responsibilities involve both technical and sales support activities. The successful candidate will assist with the training of technologists and radiologists in the operation of PET and should have in-depth knowledge of PET products and be able to provide technical training. In addition, they should have significant clinical knowledge of PET in order to consult on scanning with physicians, department heads and technical personnel. Must be willing to travel. Please submit cover letter, resume and salary requirements to:

> ALLIANCE IMAGING, INC. ATTENTION: DON WOODWARD 4912 HIGBEE AVE., NW CANTON, OH 44718

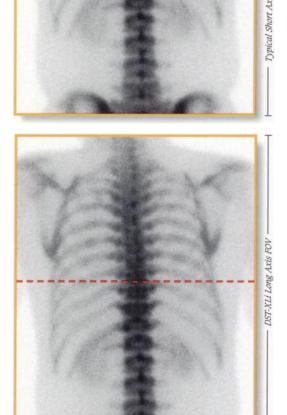
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The Nuclear Medicine Company

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