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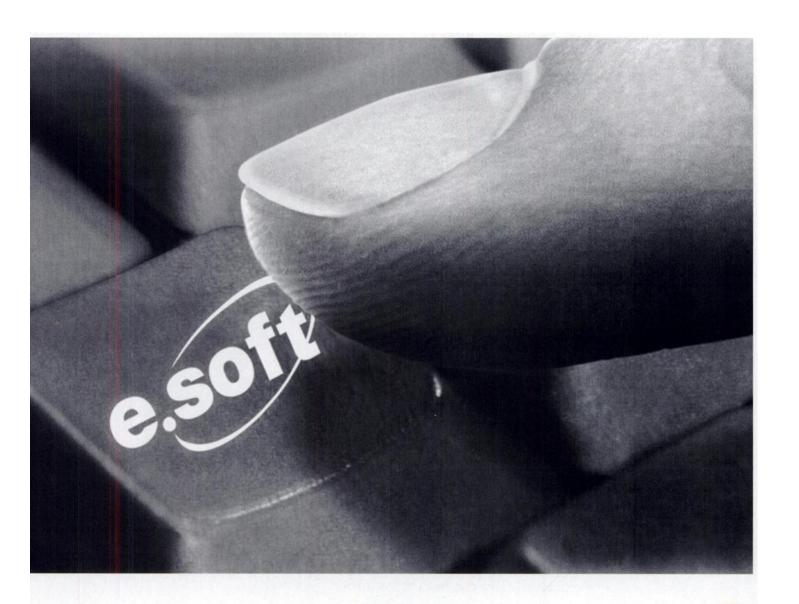


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# See your way clear

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# Guiding you to optimal intervention for neuroendocrine tumors

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

The accepted standard for GEP\* tumors

An emerging choice for small cell lung cancer

\*Gastroentero-pancreatic neuroendocrine tumors



**OCTREOSCAN®** 

Kit for the Preparation of Indium In-111 Pentetreotide

Please see adjacent page for brief summary of prescribing information.



# Kit for the Preparation of Indium In-III Pentetreotide

# **BRIEF SUMMARY OF** PRESCRIBING INFORMATION

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.
- 2) A 10-mL vial of Indium In-111 Chloride Sterile Solution.

Indium In-111 pentetrectide 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.

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

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

# **PRECAUTIONS**

### General

- Therapy with octreotide acetate can produce severe hypoglycemia in patients with insulinomas. Since pentetreotide is an analog of octreotide, an intravenous line is recommended in any patient suspected of having an insulinoma. An intravenous solution containing glucose should be administered just before and during administration of indium In-111 pentetreotide.
- The contents of the two vials supplied with the kit are intended only for use in the preparation of indium In-111 pentetreotide and are NOT to be administered separately to the patient.
- 3. Since indium In-111 pentetrectide is eliminated primarily by renal excretion, use in patients with impaired renal function should be carefully considered.
- 4. To help reduce the radiation dose to the thyroid, kidneys, bladder, and other target organs, patients should be well hydrated before the administration of indium In-111 pentetreotide. They should increase fluid intake and void frequently for one day after administration of this drug. In addition, it is recommended that patients be given a mild learning, blescody for factulose) before and after administration of indium In-111 pentetreotide (see Dosage and Administration section).
- Indium In-111 pentetrectide 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
- 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 inclum In-111 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 weatness. 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 eite pain, diarrhea, abdominal pain/discomfort, loose stools, and vomiting. Hypertension and hyper- and hypoglycemia have also been reported with the use of octreotide.

# DOSAGE AND ADMINISTRATION

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

for 48 hours. Ample fluid uptake is necessary during this period as a support boon 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 mCi) of indium In-111 pentetreotide prepared from an OctreoScan kit. The recommended intravenous dose for <u>SPECT</u> imaging is 222 MBq (6.0 mCi) of indium In-111 pentetreotide.

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

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

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

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

# **Radiation Dosimetry**

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

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium In-111 Pentetreotide's 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<br>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<br>Intestine      | 5.80   | 0.58 | 11.59  | 1.16  |
| Lower Large<br>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*<br>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. Kooij, W.A.P. Breeman, H.Y.Oei, M. de Jong, J.C. Reubi, T.J. Visser, C. Bruns, D.J. Kwekkeboom, A.E.M. Reijs, P.M. van Hagen, J.W. Koper, and S.W.J. Lamberts, "Somatostatin Rece Scrittgraphy with Indium-111-DTPA-D-Phe-1-Octreotide in Man: Metabolism, Dosimetry and Comparison with lodine-122-Tyr-3-Octreotide, The Journal of Nuclear Medicine, Vol. 33, No. 5, May 1992, pp. 652-658.
- 3. Assumes 4.8 hour voiding interval and International Commission on Radiological Protection (ICRP) 30 model for the gastrointestinal tract calculations.
- 4. Estimated according to ICRP Publication 53.

# HOW SUPPLIED

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

- The OctreoScan kir, NDC 0019-9050-40, is supplied with the bollowing components:

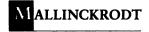
  1. A 10-m. OctreoScan Reaction Vial which contains a hyophilized mixture of:

  (i) 10 µg pentetreotide [N-(diethylenetriamine-N.N.N.N-letracetic acid-N\*-acetyl-D-phenylalaryl-L-hemicystyl-L-phenylalaryl-D-phyptophyl-L-hysyl-L-threomyl-L-hemicystyl-L-threomyl-L-hemicystyl-L-phenylalaryl-D-phyptophyl-L-hysyl-L-threomyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicystyl-L-hemicys

Before hypohilization, 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 MBg/mL (3.0 mC/mL) indium In-111 chloride in 0.2 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 package insert.



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

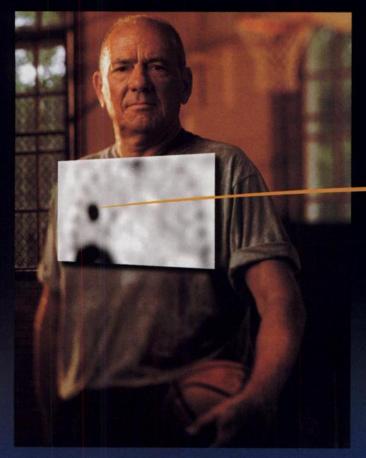
1. Termanini B, Gibril F, Reynolds JC, et al. Value of Somatostatin Receptor Scintigraphy: A Prospective Study in Gastrinoma of its Effect on Clinical Management. Gastroenterology 1997;112:335-337.

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MI22701

12/97

# **Upon Suspicion of Pulmonary Malignancy**



Neolection

Kit for the Preparation of Technetium Tc 99m Depreotide Injection

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)<sup>1</sup>
- 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.

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 Deprectide, 5 mg of sodium glucoheptonate dihydrate, 50 µg of stannous chloride dihydrate (with a rum stannous tin content of 15 µg), 100 µg edetate disodium dihydrate, and sufficient sodium hydroxide or hydrochloric acid for adjustment to pH 7.4 prior to lyophilization. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no

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

 $\textbf{NeoTect}^{\textbf{TM}}$  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**

# WARNINGS

# **PRECAUTIONS**

omatostatin analogues can produce severe hypoglycemia in patients with insulinomas. Since Depreotide binds to somatostatin 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 immuse. 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 immunoglobulins, complement, lymphokines or cytokines were not studied.

Technetium Tc 99m Deprectide 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 manageme

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.

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

Injection was administered to parents receiving concountant institutions.

Carcinogenesis, Metagenesis, 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 micronucleus assav.

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 Deprectide 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 Deprectide Injection is excreted in human milk. Caution should be exercised when Technetium Tc 99m Deprectide Injection is administered to a nursing woman. Wherever possible, infant formula should be substituted for breast milk until the technetium has been eliminated.

Safety and effectiveness of Depreotide 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 Deprectide Injection.

| 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, hymphocytosis, malaise, pharyngitis, somnolence, taste

### DOSAGE AND ADMINISTRATION

For imaging, NeoTect™ is administered as a perioheral 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 Deprectide 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 Estis         | 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.

NDC 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.

NeoTect™ is a trademark of Diatide, Inc.

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# Now we want your Whole Body!

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# **BRIEF SUMMARY OF PRESCRIBING INFORMATION**

Please consult Full Product Information before using

# DESCRIPTION

AcuTect\*\*, Kir 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 sterile, nonpyrogenic hyophilized mixture which is formulated with 100 µg of bibapcitide, 75 mg of sodium gluocheptorate dihydrate, 89 µg of stannous chloride dihydrate, and sufficient sodium hydroxide or hydrochloric acid to adjust the pH to 7.4 prior to hyophilization. The hyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product does not contain an antimicrobial preservative.

Bibepcitide 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 bibepcitide is split and forms a technetium-99m commlex of particle.

INDICATIONS AND USAGE: AcuTect<sup>IM</sup> is indicated for scintigraphic imaging of acute venous thrombosis in the lower extremities of petients who have signs and symptoms of acute venous thrombosis.

# CONTRAINDICATIONS: None known.

WARNINGS: Clinical follow-up studies of petients with negative AcuTect™ scans have not been performed to determine if negative image findings mean the absence of acute venous thrombosis. If a petient 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**

### Concret

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 petient 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 heve 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 petients 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 Acuticct<sup>M</sup> 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<sup>TM</sup> injection. To help protect themselves and others in their environment, petients need to take the following precarritions for 12 hours following injection. Wherever possible, a diet 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 wesh 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 activeted platelets has not been studied.

The effect of heperin, warfarin, or aspirin on apcitide binding has not been studied in humans. In animal in vitro and ex vivo models, heperin or aspirin did not change the inhibition of platelet aggregation caused by apcitide. Whether heperin or aspirin change the ability of apcitide to bind to GPIBO/Itla 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 lymphome test, and it was not clastogenic in the mouse micronucleus test.

# Prognancy

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 woman 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 formule should be substituted for breast milk until the technetium has been elimineted.

# 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 mCl 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 apcified, 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 systotic 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 ACCUTOCO™ 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<sup>™</sup> included: agitation, asthenia, bradycardia, cardiovascular disorder, chills, convulsions, dizziness, fever, hypertonia, injection site reaction, liver enzyme elevation, neusea, pellor, peresthesia, pruritus, sweet, 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, sortupulous 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 Imagina

AcuTect<sup>™</sup> 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<sup>™</sup> 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       | 0.6043        |  |  |
| 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 viel 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 eveilable in packs of 5 viels.

# Storag

Store the kirt 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

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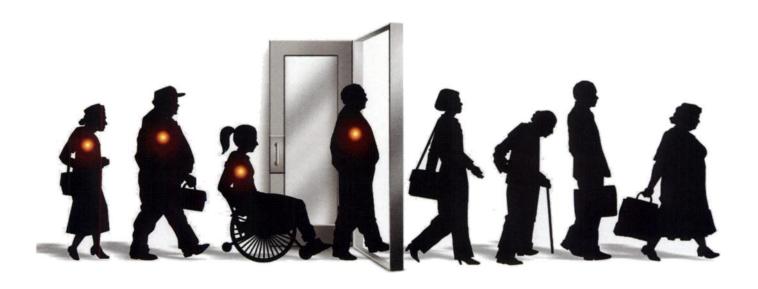
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In studying patients with known or suspected coronary artery disease, care should be taken to ensure continuous cardiac monitoring and the availability of emergency cardiac treatment.

 $\label{eq:Please see Brief Summary of Prescribing Information on adjacent page.$ 

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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 FVV, 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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BS-43-1011A

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

# R<sub>X</sub> 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 infarcted myocardium. Each vial contains a predispensed, sterile, non-pyrogenic, lyophilized mixture of 0.23 mg tetrofosmin [6,9-bis(2-ethoxyethy)-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**

### Canaral

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 diagnoses. All planar images were blindly read; SPECT images were evaluated by the unblinded investigator. A subset of 181/252 (71%) patients had coronary anglography 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 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 sulphosalicytate 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 periechnetate 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 mCl on the first injection and 22.4 mCl 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/mCl and µGy/MBq and assume unlary bladder emptying at 3.5 hours.

Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

|                       |         | Absorbed re     | diation dose |                  |
|-----------------------|---------|-----------------|--------------|------------------|
| •                     | Exe     | rcise           | Re           | et               |
| Target organ          | rad/mCl | μ <b>Gy/MBq</b> | rad/mCi      | μ <b>Gy/MB</b> 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 63 (Ann. ICRP 18 (1-4), 1988) and gave values of 8.61 x 10<sup>4</sup> mSV/MBq and 1.12 x 10<sup>4</sup> mSV/MBq after exercise and rest, respectively.

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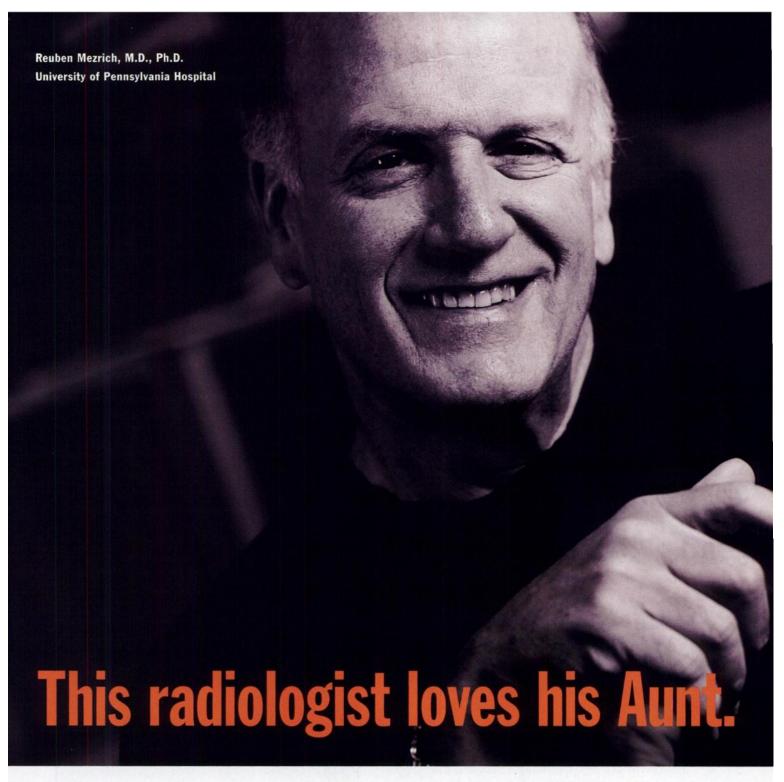
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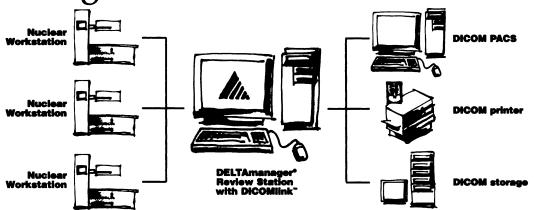




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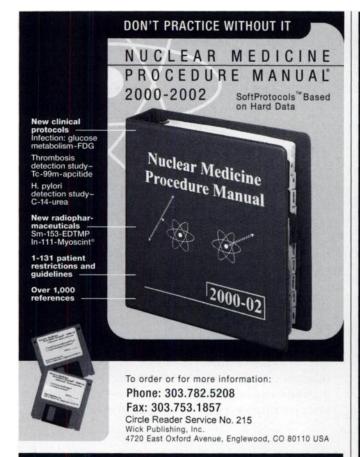
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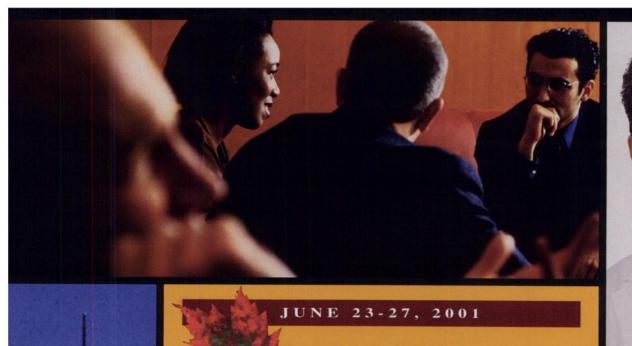
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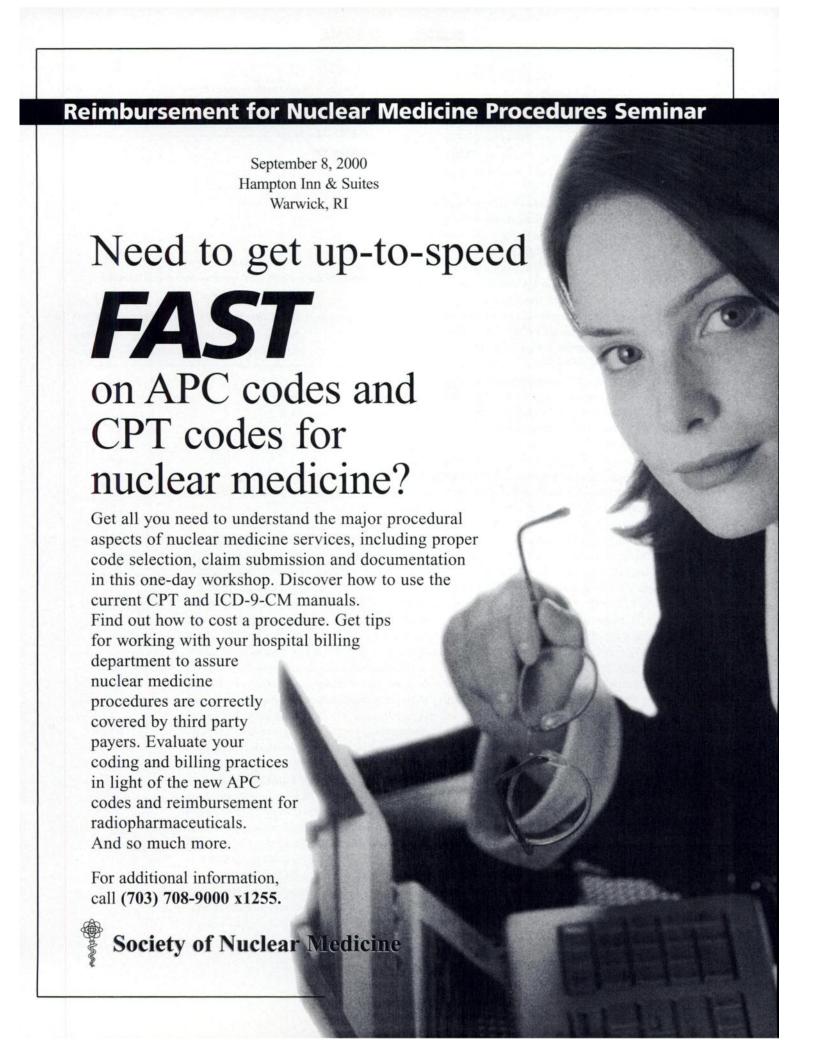
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# Paul C. Aebersold Award

Applications are invited for the 2001 Paul C. Aebersold Award for outstanding achievement in basic science applied to Nuclear Medicine. This award commemorates the contributions of Dr. Paul Clarence Aebersold to the applications of nuclear physics to Nuclear Medicine and radiation biology, as well as his contributions to the Society of Nuclear Medicine (SNM). Dr. Aebersold contributed greatly to the emergence of Nuclear Medicine as a discipline by his energetic leadership in the provision of cyclotron-generated and reactor-produced radionuclides, and by his numerous publications and lectures. In giving this award, the Society thus symbolically signifies its appreciation of the warm and vital person who became the Society's first Honorary Member.

Nominations should be supported by the nominee's curriculum vitae and at least two letters supporting the nomination. These letters should briefly describe the contributions in basic science for which the nominee is proposed. The nominee does not need to be a SNM member.

Nominations deadline: December 31, 2000. Please submit nominations and supporting documents to William J. MacIntyre, Ph.D., c/o Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, Virginia 20190-5316.

# SOCIETY OF NUCLEAR MEDICINE'S 47th ANNUAL MEETING

# AUDIO & VIDEO TAPES

# **CONTINUING EDUCATION** COURSES

\_ V00-1 (1 Video)

#1 (1 Audio) CAMERA-BASED
METHODS FOR GFR ESTIMATION --Andrew T. Taylor, Jr., MD; Gary F. Gates, MD

\_\_ V00-2 (1 Video)

#2 (1 Audio) NEW CONCEPTS IN THE THERAPY OF LYMPHOMA — James Cox, MD; Donald A. Podoloff, MD (Anas Younes, MD was not recorded)

V00-3 (1 Video)

#3 (2 Audios) MANAGEMENT OF BENIGN THYROID DISORDERS — James C. Sission, MD; I. R. McDougall, MD, PhD

\_ V00-4 (1 Video)

#4 (1 Audio) TECHNIQUE, CLINICAL ROLE AND ECONOMICS OF IMAGING CHILDREN WITH URINARY TRACT INFECTION - Robert Howman-Giles. MD: Michael J. Gelfand, MD

V00-5 (1 Video)

#5 (1 Audio) CONCURRENT MYOCARDIAL FUNCTION AND PERFUSION: IS THERE ADDITIONAL DIAGNOSTIC AND PROGNOSTIC VALUE? - Michael R. Freeman, MD; Daniel S. Berman, MD (audio tape only; not on video); Salvador Borges-Neto, MD

V00-6 (1 Video)

#6 (1 Audio) THE RELEVANCE AND ASSESSMENT OF MYOCARDIAL VIABILITY - lamshid Maddahi, MD: Rob Beanlands. MD (Steven R. Bergmann, MD, PhD was not recorded)

V00-7 (1 Video)

#7 (1 Audio) LUNG NODULES -Keith S. Naunheim, MD; Jay Blum, MD; Val J. Lowe, MD

#8 (1 Audio) QUANTIFICATION OF MYOCARDIAL PERFUSION - HOW TO APPLY A CLINICAL PRACTICE -Glibert A. Hurwitz, MD: Plotr Siomka: Ernest V. Garcia, PhD (audio tape only;

not on video); John J. Mahmarian, MD

# TECHNOLOGIST CONTINUING **EDUCATION COURSES**

V00-9 (2 Videos)

#9 (2 Audios) RADIATION SAFETY — James E. Carey, Jr., MS, DABR; Robert T. Anger, Jr., MS (Note: The Impact on the Dayto-Day Practice of Nuclear Medicine was not recorded)

V00-10 (1 Video)

#10 (1 Audio) UPDATE ON
LEGISLATIVE AND REGULATORY MATTERS IN NUCLEAR MEDICINE - William R. Uffelman, Esq.; Valerie R. Cronin, CNMT; Kathy Haney, MS; LisaAnn Trembath, BA,



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#23 (4 Tapes, \$44) **PEDIATRIC** NUCLEAR MEDICINE: ADVANCES FOR THE NEW MILLENNIUM

\_\_\_ #24 (3 Tapes, \$33) 101 FDG PET/ SPECT - CLINICAL ADVANCES IN PET/

# CONTINUING EDUCATION COURSES

#25 WHOLE BODY PET FDG IN CANCER PATIENTS - READ WITH THE EXPERTS (R. Edward Coleman, MD was not

\_\_\_ #26 RADIOBIOLOGICAL EFFECTS OF IONIZING RADIATION (REIR) CONTINUING EDUCATION: RADIOBIOL-

#27 SCINTIMAMMOGRAPHY -READ WITH THE EXPERTS

\_\_\_ #28 V/Q AND HELICAL CT IN THE DIAGNOSIS OF PULMONARY EMBOLISM

#29 RADIOBIOLOGICAL EFFECTS OF IONIZING RADIATION (REIR)
CONTINUING EDUCATION: RADIOBIOLOGY II

\_\_\_\_ #30 MAKING MYOCARDIAL PERFUSION SPECT INTERPRETATIONS CLINICALLY RELEVANT - READ WITH THE **EXPERTS** 

#31 ACUTE ABDOMINAL PAIN: DIAGNOSTIC DILEMMAS

#32 CALCULATION OF ABSORBED DOSE: FROM INTERNAL DOSE TO RELEASING PATIENTS FROM THE HOSPITAL (Richard B. Sparks, PhD was not recorded)

\_\_\_\_ #34 INTERPRETING VENTRICULAR FUNCTION STUDIES - READ WITH THE EXPERTS

#35 FEDERAL AGENCIES AND NUCLEAR MEDICINE

#36 PARATHYROID LOCALIZATION

#37 SPECT BRAIN IMAGING PRACTICA: TECHNICAL ASPECTS

#38 MONOCLONAL ANTIBODIES IN ONCOLOGY - READ WITH THE EXPERTS

#39 MYOCARDIAL PERFUSION IMAGING IN ACUTE CORONARY SYNDROMES

\_\_\_\_ #40 (2 Tapes, \$22)
COST-EFFECTIVENESS OF FDG PET IN ONCOLOGY

\_\_\_\_ #41 SPECT BRAIN IMAGING PRACTICA: ROUTINE CLINICAL APPLICATIONS

#42 COST-EFFECTIVE DIAGNOSIS OF CORONARY ARTERY DISEASE (Robert C. Hendel, MD was not recorded)

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V00-11 (4 Videos)

#11 (4 Audios) CLINICAL POSITRON IMAGING: EXPERT FORUM —
Paul C. Hanson, CNMT, PSNMTS; Steve

Torres, RPH; Steve Kohlmyer, MS; Lonnie M. Mixon; Pat Devlin, CNMT; Donald M. Torre. CNMT; Andre Vanuffel (Claire T. Terry, DCR, RT and Jon Frey were not recorded)

V00-12 (1 Video)

\_\_\_\_ #12 (1 Audio) SENTINEL NODE IMAGING AND TECHNIQUES — Douglas Murray, MD; Patti L. Corrigan-Langford, CNMT

# AUDIO TAPES ONLY

#13 PLENARY SESSION --R. Edward Coleman

\_\_\_ #14 (2 Tapes, \$22)
ANNUAL MEETING HIGHLIGHTS — Henry N. Wagner, MD

# **CATEGORICAL SEMINARS**

#15 (3 Tapes, \$33) FEDERAL GRANT FUNDING FOR BIOMEDICAL IMAGING

#16 (4 Tapes, \$44) EVALUATING PET SCANNERS FOR CLINICAL USE

#17 (4 Tapes, \$44) THE ROLE OF NUCLEAR CARDIOLOGY IN 2000

\_\_\_ #18 (2 Tapes, \$22) 101 FDG PET/ SPECT – FUNCTIONAL IMAGING AND **CLINICAL ADVANCES** 

\_\_\_ #19 (3 Tapes, \$33) FDA REGULA-TORY FRAMEWORK FOR PET

#20 (4 Tages, \$44) CUTTING EDGE OF CLINICAL NUCLEAR MEDICINE

#21 (3 Tapes, \$33) THE USE OF ALPHA-EMITTING ISOTOPES IN PRE-CLINICAL AND CLINICAL TRIALS (Ronald D. Finn, PhD; Marco Chinol, PhD; and Michael R. Zalutsky, PhD were not recorded)



# **AUDIO TAPES ONLY**

# CONTINUING EDUCATION COURSES

\_\_\_ #43 (2 Tapes, \$22) UPDATES IN IMAGING AND THERAPY OF THYROID CARCINOMAS

\_\_\_ #44 SPECT BRAIN IMAGING PRACTICA: ADVANCED CLINICAL APPLICATIONS

\_\_\_ #45 FDG IMAGING ON PET CAMERAS - READ WITH THE EXPERTS

\_\_\_\_ #46 ATTENUATION CORRECTION IN CARDIAC STUDIES (Robert C. Hendel, MD was not recorded)

#47 GENE THERAPY

\_\_\_\_ #48 CAMERA QC AND ACCEP-TANCE TESTING: ADVICE FOR THE NOVICE

\_\_\_\_\_ #49 (2 Tapes, \$22) UPDATE IN GENERAL NUCLEAR MEDICINE — THE ALASHIMN PERSPECTIVE — AN INTERACTIVE SESSION

\_\_\_\_ #50 SUCCESSFULLY ESTABLISHING A HYBRID PET IMAGING CENTER IN THE COMMUNITY SETTING

\_\_\_\_\_ #51 LYMPHOSCINTIGRAPHY: BASIC CONCEPTS, RADIOPHARMACEUTICALS AND TECHNICAL CONSIDERATIONS

\_\_\_ #52 PACS - HOW TO CHOOSE ONE

\_\_\_\_ #53 MYOCARDIAL PERFUSION
SPECT: HOW TO DIFFERENTIATE REALITY
FROM ARTIFACT - READ WITH THE
EXPERTS

\_\_\_ #54 MULTIMODALITY APPROACH TO STAGE LYMPHOMA

\_\_\_\_ #55 PEDIATRICS - READ WITH THE EXPERTS

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\_\_\_\_\_ #56 EMERGING ROLE OF RADIO-PHARMACELITICAL SURROGATES IN THE ASSESSMENT OF THEMAPEUTIC PHARMACELITICALS

\_\_\_ #57 TELEMEDICINE: A LEGAL POINT OF VIEW

\_\_\_ #58 ABSORBED DOSE ESTIMATES: FROM CLINICAL IMPORTANCE TO TREATMENT PLANNING (Michael G. Stabin, PhD was not recorded)

\_\_\_\_ #59 HOW TO IDENTIFY
MYOCARDIAL VIABILITY - READ WITH
THE EXPERTS

\_\_\_\_ #60 SOMATOSTATIN-BASED IMAGING AND THERAPY (Eric P. Krenning, MD. PhD was not recorded)

\_\_\_\_\_ #61 COST-EFFECTIVENESS IN ONCOLOGY/CARDIOLOGY (Jamshid Maddahl, MD was not recorded)

\_\_\_\_ #62 (2 Tapes, \$22) BRAIN CONTINUING EDUCATION COURSE — READ WITH THE EXPERTS

\_\_\_\_ #64 BASIC PRINCIPLES OF COST-EFFECTIVENESS OVER OUTCOMES STUDIES

\_\_\_\_\_ #66 ACQUISITION AND PROCESS-ING OF MYOCARDIAL PERFUSION STUDIES IN THE YEAR 2000

\_\_\_\_ #67 (2 Tapes, \$22) THE SENTINEL LYMPH NODE IN SURGICAL ONCOLOGY

\_\_\_\_ #68 THE DECISION MAKING PROCESS: UNDERSTANDING THE LITERATURE

\_\_\_ #69 GRANT FUNDING

\_\_\_\_ #70 BASIC PRINCIPLES AND TECHNICAL CONSIDERATIONS OF MULTI-HEAD GAMMA COINCIDENCE IMAGING \_\_\_ #71 THE BUSINESS OF MEDICINE:

# TECHNOLOGIST CONTINUING EDUCATION COURSES

\_\_\_\_\_#72 (3 Tapes, \$33) EMERGING LEADERS CONFERENCE (Marcia R. Boyd, CNMT. FSNMTS was not recorded)

\_\_\_ #73 (3 Tapes, \$33) TECHNOLOGIST CERTIFICATION EXAM: REVIEW SESSION I

\_\_\_\_\_ #74 (4 Tapes, \$44) CLINICAL NUCLEAR MEDICINE IN THE NEW MILLENNIUM (Jamshid Maddahi, MD was not recorded)

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MEDICINE ENHANCING PHARMACEUTICALS AND THE ROLE OF THE TECHNOLOGIST

\_\_\_ #80 EDUCATOR'S FORUM

\_\_\_\_ #81 EDUCATOR'S FORUM: JRCNMT WORKSHOP

\_\_\_\_ #82 PEPTIDE ADVANCES IN THE DIAGNOSIS AND TREATMENT OF LUING CANCER

\_\_\_ #83 EDUCATOR'S FORUM: AMERICANS WITH DISABILITIES ACT

\_\_\_\_ #84 (2 Tapes, \$22) TS CARDIAC SESSION I

\_\_\_\_ #85 (4 Tapes, \$44) BREAST CANCER OVERVIEW

\_\_\_ #87 TS CARDIAC SESSION II

\_\_\_ #88 EDUCATOR'S FORUM: STUDENT EVALUATION

#89 TS CARDIAC SESSION III

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\_\_\_\_ #93 (2 Tapes, \$22) BRINGING BRAIN IMAGING TO YOUR CLINIC

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# **Nuclear Medicine Technologist**

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currently seeking a full time technologist. Must be licensed and ARRT(N) or NMTCB certified. Must have knowledge of gated cardiac SPECT imaging, and understanding of non-cardiac nuclear procedures. Must be compliant with NRC regulations. Must work well with ancillary staff members, be self motivated and work without supervision. Challenging position with no call, flexible hours and full benefits. Experience with ADAC systems a plus. Inquiries contact Becky Johnson at (801) 429-8035, HR Director. Mail: 1055 North 500 West, Provo, UT 84604. Fax: (801) 374-2615. E-mail: meic21216@yahoo.com.

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# **Nuclear Medicine Technologist**

FT position in our Marysville facility for ARRT &/or NMTCB Basic Life Support certified candidate. Prev. exp. pref, new grads ok. No weekend or on call. Fax or e-mail resume to (530) 749-3473, or www.sutternorth.org. EOE.

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Applications will be accepted through September 15, 2000.

Send letters to:

University of Minnesota, Marvin E. Goldberg, MD
Associate Professor of Radiology, Department of Radiology
Box 292 Mayo Bldg.
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Minneapolis, MN 55455

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# **NUCLEAR MEDICINE**

The Dept. of Radiology at Wayne State University and the Detroit Medical Center is currently recruiting an ABR-certified nuclear radiologist with addition ABNM certification or ABR special competence in nuclear radiology. The candidate must be also be able to cross over in general and cross-sectional radiology. The position is available July 1, 2000. The dept. offers an extremely competitive compensation package as well as an opportunity to actively participate in its teaching and research programs.

Interested candidates should send a current CV and introductory letter to:

Lawrence P. Davis, MD, F.A.C.R, Interim Chair Dept. of Radiology DRH 3L8 4201 St. Antoine Detroit, MI 48201

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Bassett Healthcare
One Atwell Road
Cooperstown, NY 13326

E-mail to joan.lee@bassett.org or call toll free at (800) 526-1271 for more information.

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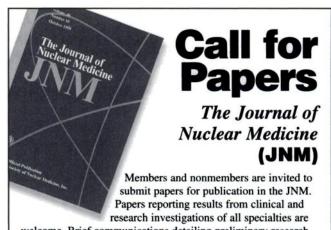
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# **NUCLEAR MEDICINE PHYSICIAN**

The Department of Radiology at Stanford University is seeking a board certified Nuclear Medicine physician for a full-time faculty member in the Nuclear Medicine Service at the Palo Alto Veterans Affairs Health Care System. Applicants must be a U.S. citizen. The individual will hold an appointment as an Assistant Professor in the Medical Center Line at Stanford University in addition to the primary appointment at the VA. The Nuclear Medicine Service at the VA Palo Alto Hospital was opened in 1999, and is equipped with a dedicated PET scanner, on-site clinical cyclotron, and coincident capable gamma cameras. The individual should be American Board of Radiology certified, have training and experience in single photon and positron emission tomographic imaging, in-vivo and in-vitro general nuclear medicine procedures, as well as radionuclide therapy. The individual will have responsibility for daily clinical activities at the VA, as well as the education and training of residents in Nuclear Medicine and Radiology. The successful candidates will establish a strong clinical research program through collaborative efforts and participation in interdepartmental programs. In addition to the facilities at the VA, interdepartmental resources include a newly established molecular imaging program with plans for a micro-PET and micro-SPECT, a hospital wide PAC's system, and the establishment of a PET program at Stanford. Stanford University is committed to increasing representation of women and members of minority groups on its faculty and particularly encourages applications from such candidates. Applicants should submit an introductory letter, curriculum vitae and the names and addresses of three references to:

H. William Strauss, MD

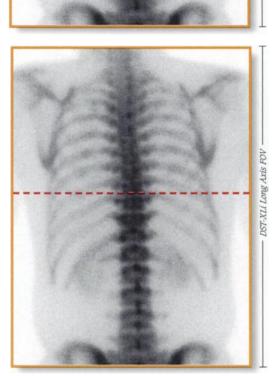
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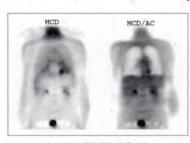
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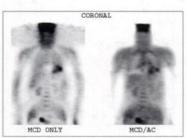
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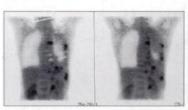




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