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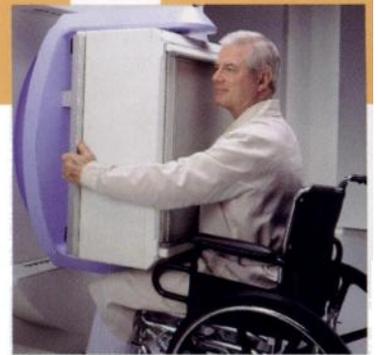
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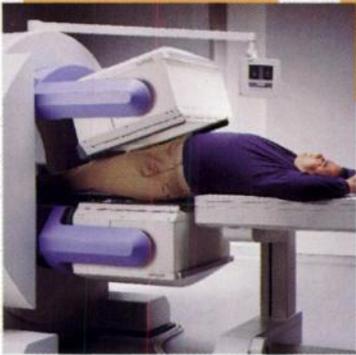
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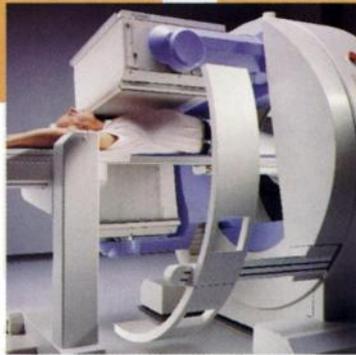


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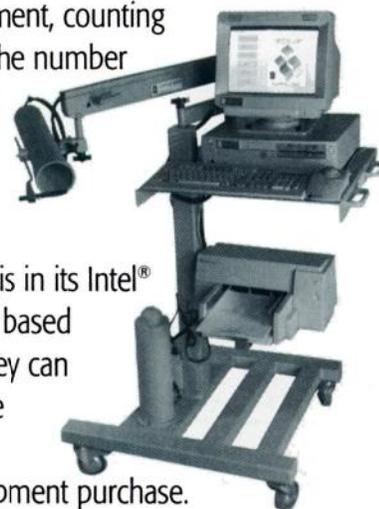
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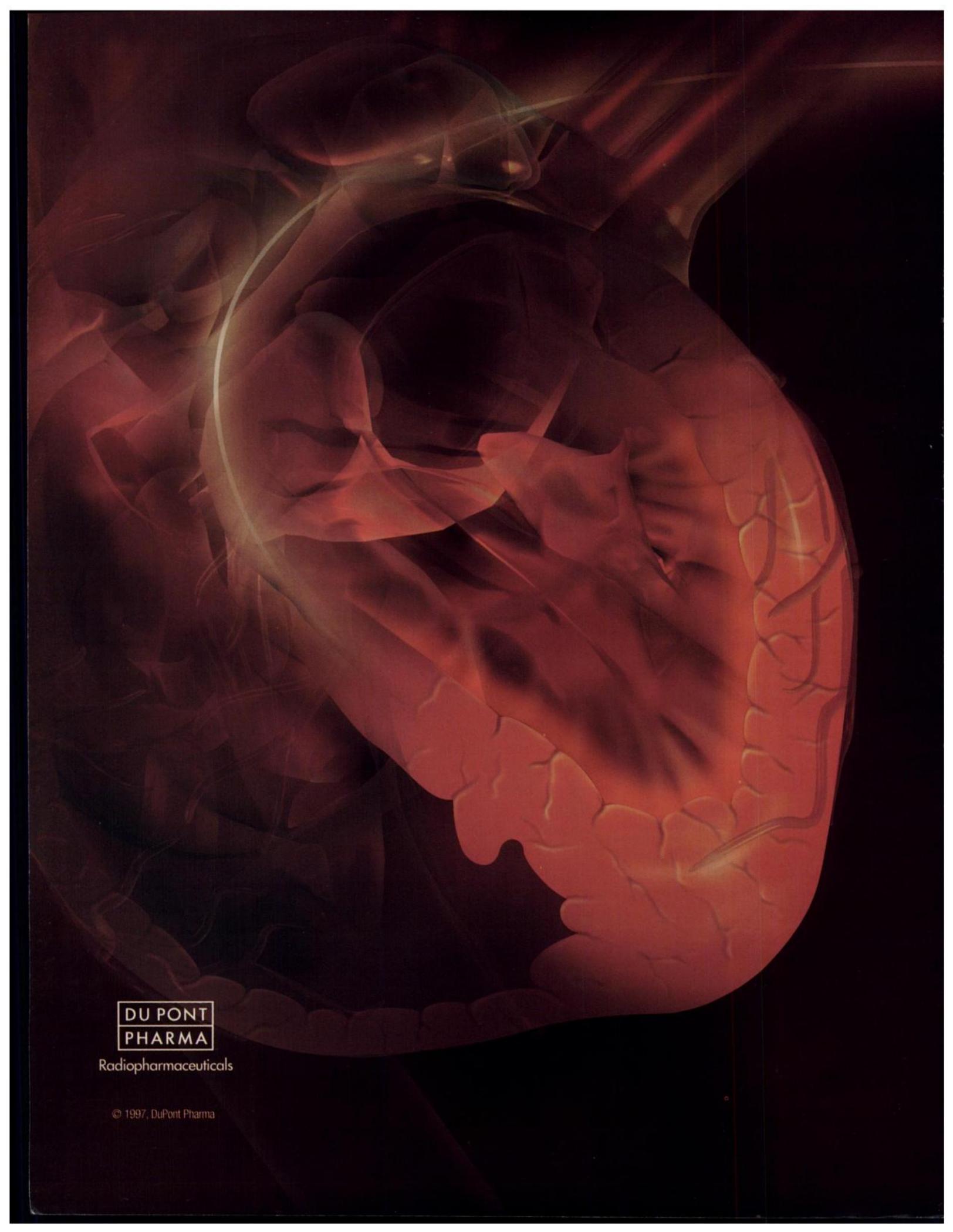


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Radiopharmaceuticals

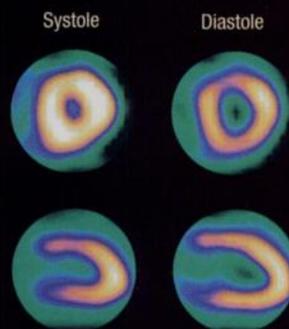
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Inside Information.

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There have been infrequent reports of signs and symptoms consistent with seizure and severe hypersensitivity after administration of Tc99m Sestamibi. Please see brief summary of prescribing information on adjacent page.

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

The Confidence You Want—The Information You Need

Brief Summary

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects), in evaluating myocardial function and developing information for use in patient management decisions. CARDIOLITE® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (e.g., exercise or pharmacologic stress in accordance with the pharmacologic stress agent's labeling).

It is usually not possible to determine the age of a myocardial infarction or to differentiate a recent myocardial infarction from ischemia.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (See PRECAUTIONS).

Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, arrhythmias, hypotension, bronchoconstriction and cerebrovascular events. Caution should be used when pharmacologic stress is selected as an alternative to exercise; it should be used when indicated and in accordance with the pharmacologic stress agent's labeling.

PRECAUTIONS:

GENERAL

The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure.

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Sodium Perchnetate Tc99m Injection is added, adequate shielding of the final preparation must be maintained.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Perchnetate Tc99m Injection containing oxidants should not be used.

Technetium Tc99m Sestamibi should not be used more than six hours after preparation.

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

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

The most frequent exercise stress test endpoints, which resulted in termination of the test during controlled Tc99m Sestamibi studies (two-thirds were cardiac patients) were:

Fatigue	35%
Dyspnea	17%
Chest Pain	16%
ST-depression	7%
Arrhythmia	1%

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5rads/30mCi at rest, 1.2 rads/30mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE AND ADMINISTRATION section.)

The active intermediate, [Cu(MIBI)₄]BF₄, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all *in vitro*). At cytotoxic concentrations (≥ 20μg/ml), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. [Cu(MIBI)₄]BF₄ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/kg, > 600 × maximal human dose).

Pregnancy Category C

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

Nursing Mothers

Technetium Tc99m Perchnetate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient parosmia and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing, edema, injection site inflammation, dyspepsia, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, and hypotension also have been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (see WARNINGS and PRECAUTIONS). The following adverse reactions have been rarely reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis in a wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthenia and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

DOSAGE AND ADMINISTRATION: The suggested dose range for I.V. administration in a single dose to be employed in the average patient (70kg) is:

370-1110MBq (10-30mCi)

The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (see also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration (see also CLINICAL PHARMACOLOGY).

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Radiochemical purity should be checked prior to patient administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Store at 15-25°C before and after reconstitution.

RADIATION DOSIMETRY: The radiation doses to organs and tissues of an average patient (70kg) per 1110MBq (30mCi) of Technetium Tc99m Sestamibi injected intravenously are shown in Table 4.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

Organ	Estimated Radiation Absorbed Dose			
	REST		STRESS	
	2.0 hour void		4.8 hour void	
	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.9
Gallbladder Wall	2.0	20.0	2.0	20.0
Small Intestine	3.0	30.0	3.0	30.0
Upper Large Intestine Wall	5.4	55.5	5.4	55.5
Lower Large Intestine Wall	3.9	40.0	4.2	41.1
Stomach Wall	0.6	6.1	0.6	5.8
Heart Wall	0.5	5.1	0.5	4.9
Kidneys	2.0	20.0	2.0	20.0
Liver	0.6	5.8	0.6	5.7
Lungs	0.3	2.8	0.3	2.7
Bone Surfaces	0.7	6.8	0.7	6.4
Thyroid	0.7	7.0	0.7	6.8
Ovaries	1.5	15.5	1.6	15.5
Testes	0.3	3.4	0.4	3.9
Red Marrow	0.5	5.1	0.5	5.0
Urinary Bladder Wall	2.0	20.0	4.2	41.1
Total Body	0.5	4.8	0.5	4.8

Radiopharmaceutical Internal Dose Information Center, July, 1990, Oak Ridge Associated Universities, P.O. Box 117, Oak Ridge, TN 37831, (615) 576-3449.

HOW SUPPLIED: Du Pont Radiopharmaceutical's CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi is supplied as a 5ml vial in kits of two (2), five (5) and thirty (30) vials, sterile and non-pyrogenic.

Prior to lyophilization the pH is between 5.3-5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at 15-25°C before and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each five (5) vial kit are one (1) package insert, six (6) vial shield labels and six (6) radiation warning labels. Included in each thirty (30) vial kit are one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material pursuant to section 35.11 and section 35.200 of Title 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.



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Billerica, Massachusetts, USA 01862

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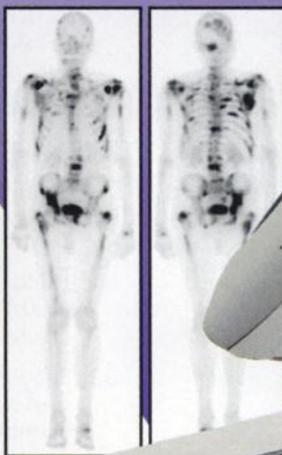
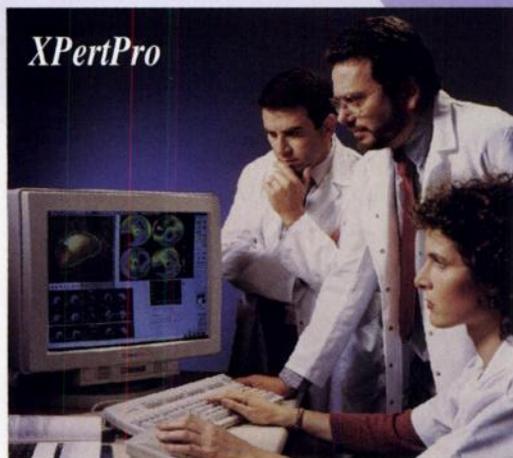
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2/96

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VariCam

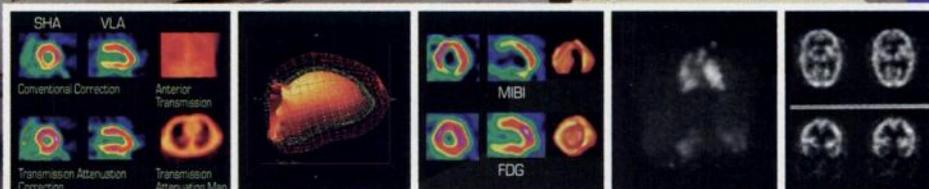
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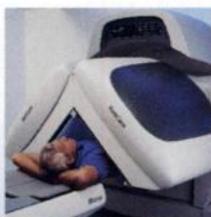
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Cardiology



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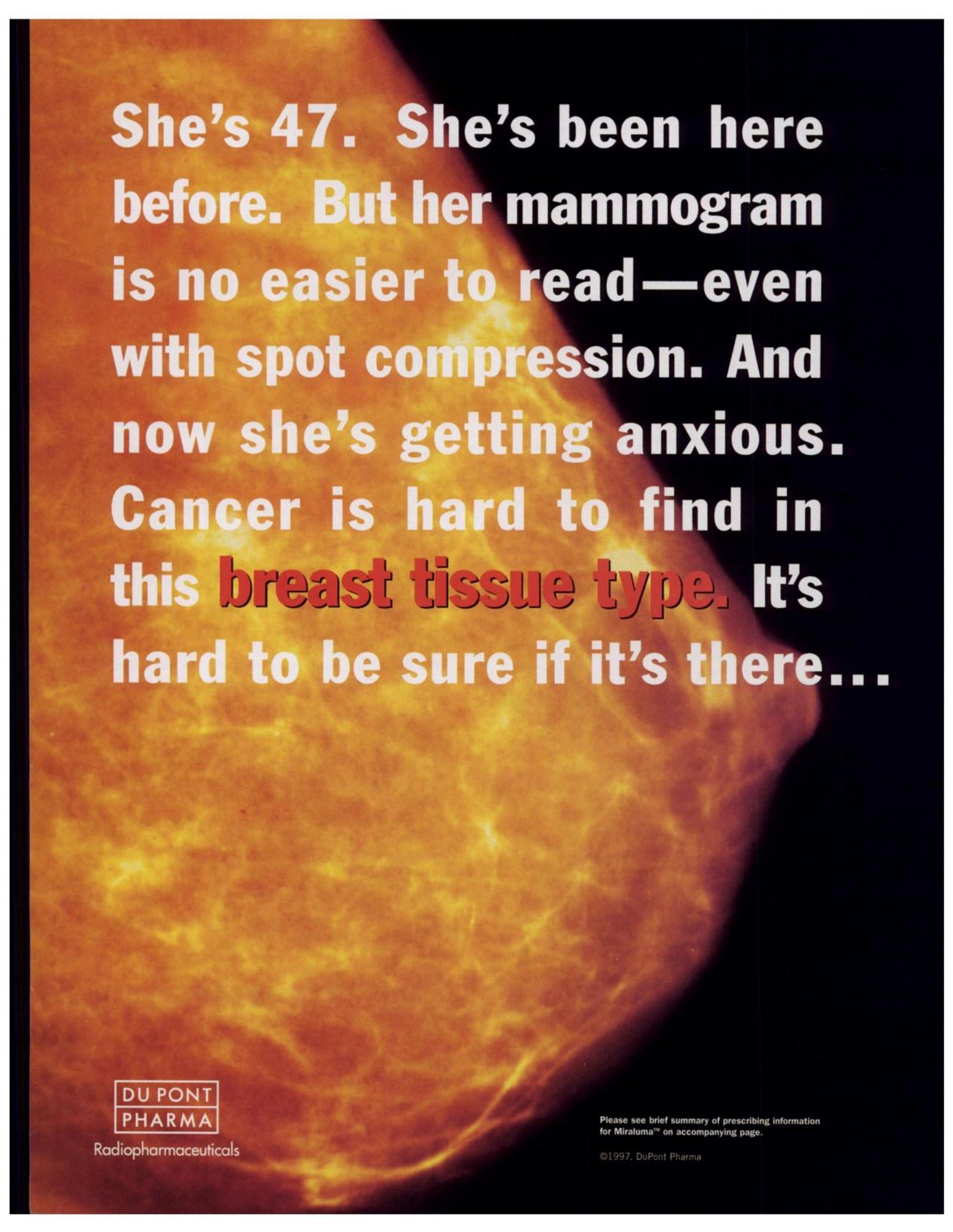


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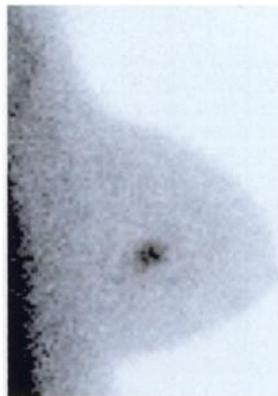
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Please see brief summary of prescribing information for Miraluma™ on accompanying page.

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is it there?



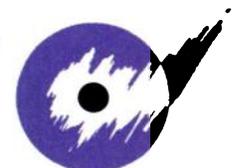
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The diagnostic sensitivity of Miraluma™ is decreased in tumors <1 cm in largest dimension. There have been rare reports of signs and symptoms consistent with severe hypersensitivity and seizure after administration of Technetium Tc 99m Sestamibi.

For more information, call Technical Services at 1-800-635-2683 or access the DuPont Radiopharmaceuticals Web site at www.radiopharm.com

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FOR DIAGNOSTIC USE

INDICATIONS AND USAGE: Breast Imaging: MIRALUMA™, Kit for the Preparation of Technetium Tc99m Sestamibi, is indicated for planar imaging as a second line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass.

MIRALUMA™ is not indicated for breast cancer screening, to confirm the presence or absence of malignancy, and it is not an alternative to biopsy.

Myocardial Imaging: CARDIOLITE®. Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects), in evaluating myocardial function and developing information for use in patient management decisions. CARDIOLITE® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (e.g., exercise or pharmacologic stress in accordance with the pharmacologic stress agent's labeling).

It is usually not possible to determine the age of a myocardial infarction or to differentiate a recent myocardial infarction from ischemia.

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom cardiac disease is known or suspected, care should be taken to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure. Infrequently, death has occurred 4 to 24 hours after Tc99m Sestamibi use and is usually associated with exercise stress testing (See Precautions).

Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, arrhythmia, hypotension, bronchoconstriction and cerebrovascular events. Caution should be used when pharmacologic stress is selected as an alternative to exercise; it should be used when indicated and in accordance with the pharmacologic stress agent's labeling.

Technetium Tc99m Sestamibi has been rarely associated with acute severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symptoms developed on the second injection during CARDIOLITE® imaging. Patients who receive CARDIOLITE® or MIRALUMA™ imaging are receiving the same drug. Caution should be exercised and emergency equipment should be available when administering Technetium Tc99m Sestamibi. Also, before administering either CARDIOLITE® or MIRALUMA™, patients should be asked about the possibility of allergic reactions to either drug.

PRECAUTIONS:

GENERAL

The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure.

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc99m Injection is added, adequate shielding of the final preparation must be maintained.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Technetium Tc99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc99m Injection containing oxidants should not be used.

Technetium Tc99m Sestamibi should not be used more than six hours after preparation.

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

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

The most frequent exercise stress test endpoints sufficient to stop the test reported during controlled studies (two-thirds were cardiac patients) were:

Fatigue	35%
Dyspnea	17%
Chest Pain	16%
ST-depression	7%
Arrhythmia	1%

Information for Patients

CARDIOLITE® and MIRALUMA™ are different names for the same drug. Patients should be advised to inform their health care provider if they had an allergic reaction to either drug or if they had an imaging study with either drug.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5 rads/30 mCi at rest, 1.2 rads/30mCi at exercise) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE and ADMINISTRATION section.)

The active intermediate, Cu(MIBI)₄BF₄, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all *in vitro*).

At cytotoxic concentrations ($\geq 20 \mu\text{g/ml}$), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. Cu(MIBI)₄BF₄ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg, $> 600 \times$ maximal human dose).

Pregnancy Category C

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

Nursing Mothers

Technetium Tc99m Pertechnetate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS: Adverse events were evaluated in 3741 adults who were evaluated in clinical studies. Of these patients, 3068 (77% men, 22% women, and 0.7% of the patient's genders were not recorded) were in cardiac clinical trials and 673 (100% women) in breast imaging trials. Cases of angina, chest pain, and death have occurred (see Warnings and Precautions). Adverse events reported at a rate of 0.5% or greater reported after receiving Technetium Tc99m Sestamibi administration are shown in the following table:

Table 9
Selected Adverse Events Reported in $> 0.5\%$ Of Patients Who Received Technetium Tc99m Sestamibi in Either Breast or Cardiac Clinical Studies*

Body System	Breast Studies		Cardiac Studies	
	Women n = 673	Women n = 685	Men n = 2361	Total n = 3046
Body as a Whole	21 (3.1%)	6 (0.9%)	17 (0.7%)	23 (0.8%)
Headache	11 (1.6%)	2 (0.3%)	4 (0.2%)	6 (0.2%)
Cardiovascular	9 (1.3%)	24 (3.5%)	75 (3.2%)	99 (3.3%)
Chest Pain/Angina	0 (0%)	18 (2.6%)	46 (1.9%)	64 (2.1%)
ST segment changes	0 (0%)	11 (1.6%)	29 (1.2%)	40 (1.3%)
Digestive System	8 (1.2%)	4 (0.6%)	9 (0.4%)	13 (0.4%)
Nausea	4 (0.6%)	1 (0.1%)	2 (0.1%)	3 (0.1%)
Special Senses	132 (19.6%)	62 (9.1%)	160 (6.8%)	222 (7.3%)
Taste Perversion	129 (19.2%)	60 (8.8%)	157 (6.6%)	217 (7.1%)
Parosmia	8 (1.2%)	6 (0.9%)	10 (0.4%)	16 (0.5%)

* Excludes the 22 patients whose gender were not recorded.

In the clinical studies for breast imaging, breast pain was reported in 12 (1.7%) of the patients. In 10 of these patients the pain appears to be associated with biopsy/surgical procedures.

The following adverse reactions have been reported in $\leq 0.5\%$ of patients: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis; angioedema, arrhythmia, dizziness, syncope, and severe hypersensitivity characterized by dyspnea, hypotension, bradycardia, asthenia, abdominal pain, vomiting, pruritis, rash, and urticaria within two hours after a second injection of Technetium Tc99m Sestamibi. A few cases of flushing, edema, injection site inflammation, dry mouth, fever, and fatigue have also been attributed to administration of the agent.

DOSAGE AND ADMINISTRATION: For Breast Imaging: The recommended dose range for I.V. administration of MIRALUMA™ is a single dose of 740-1110 MBq (20 - 30 mCi).

For Myocardial Imaging: The suggested dose range for I.V. administration of CARDIOLITE® in a single dose to be employed in the average patient (70Kg) is 370-1110MBq (10-30mCi).



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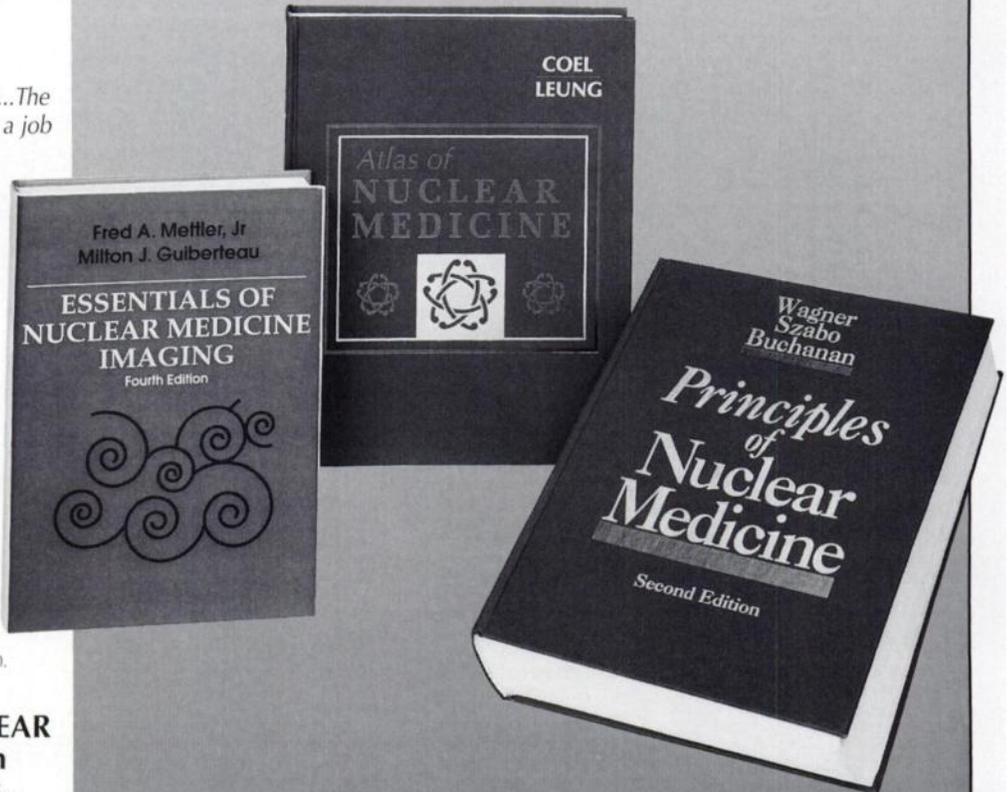
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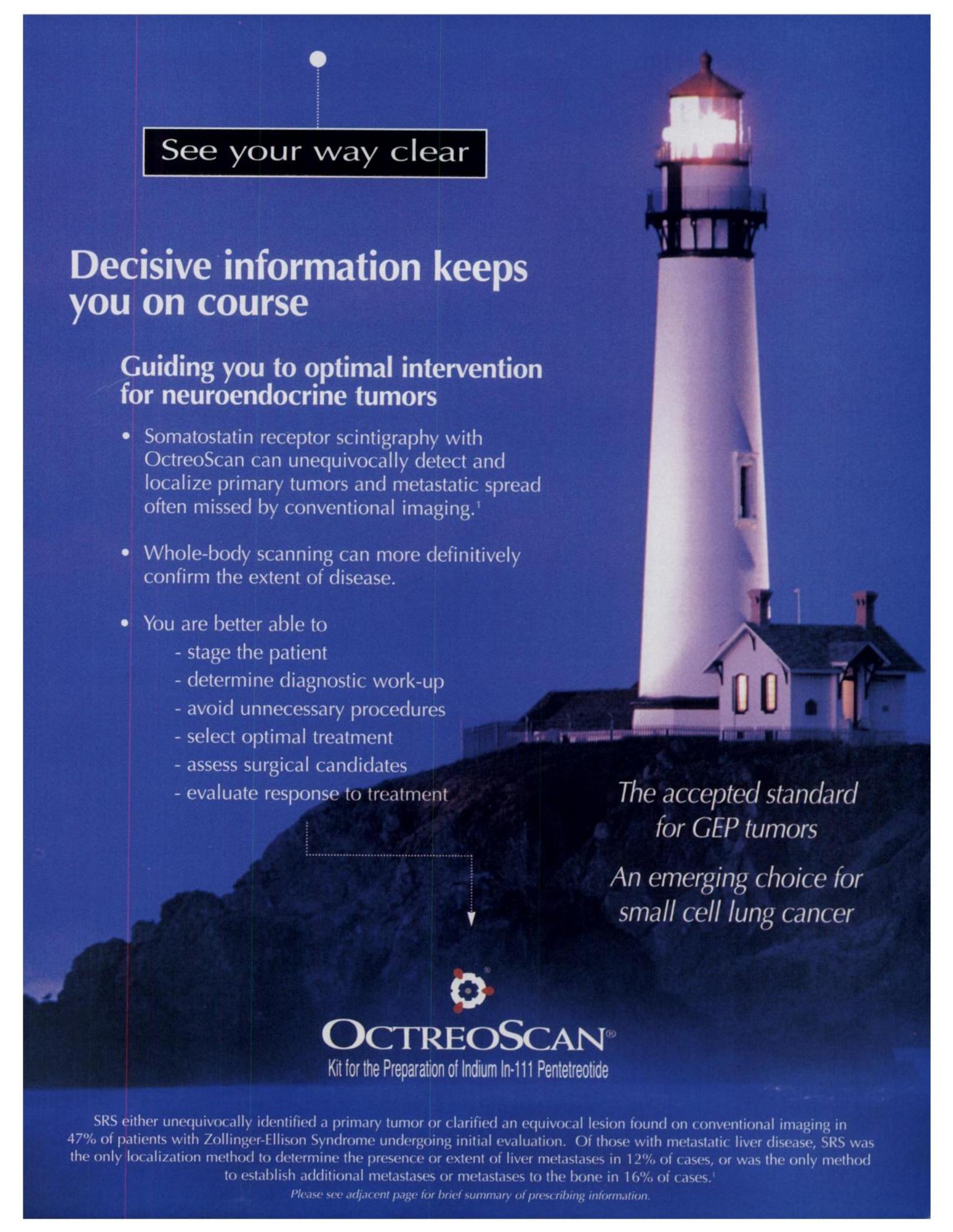
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Please see adjacent page for brief summary of prescribing information.

OCTREOSCAN[®]

Kit for the Preparation of Indium In-111 Pentetreotide

BRIEF SUMMARY OF PRESCRIBING INFORMATION

DESCRIPTION

OctreoScan[®] is a kit for the preparation of indium In-111 pentetreotide, a diagnostic 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 pentetreotide is prepared by combining the two kit components.



INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

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

PRECAUTIONS

General

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy Category C

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

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

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

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

DOSAGE AND ADMINISTRATION

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

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

The recommended intravenous dose for **planar** imaging is 111 MBq (3.0 mCi) of indium In-111 pentetreotide prepared from an OctreoScan kit. The recommended intravenous dose for **SPECT** imaging is 222 MBq (6.0 mCi) of indium In-111 pentetreotide.

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

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

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

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

Radiation Dosimetry

The estimated radiation doses¹ 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 Pentetreotide³ to a 70 kg patient

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

1. Values listed include a correction for a maximum of 0.1% indium In-114m radiocontaminant at calibration.
2. E.P. Krenning, W.H. Bakker, P.P.M. Kooij, W.A.P. Breeman, H.Y.Oei, M. de Jong, J.C. Reubi, T.J. Visser, C. Bruns, D.J. Kwekkeboom, A.E.M. Reijs, P.M. van Hagen, J.W. Koper, and S.W.J. Lamberts, "Somatostatin Receptor Scintigraphy with Indium-111-DTPA-D-Phe-1-Octreotide in Man: Metabolism, Dosimetry and Comparison with Iodine-123-Tyr-3-Octreotide," *The Journal of Nuclear Medicine*, Vol. 33, No. 5, May 1992, pp. 652-658.
3. Assumes 4.8 hour voiding interval and International Commission on Radiological Protection (ICRP) 30 model for the gastrointestinal tract calculations.
4. Estimated according to ICRP Publication 53.

HOW SUPPLIED

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

1. A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of:
 - (i) 10 µg pentetreotide [N-(diethylenetriamine-N,N,N',N'-tetraacetic acid-N'-acetyl)-D-phenylalanyl-L-hemicycstyl-L-phenylalanyl-D-tryptophyl-L-lysyl-L-threonyl-L-hemicystyl-L-threoinol cyclic (2-7) disulfide], (also known as octreotide DTPA),
 - (ii) 2.0 mg gentisic acid [2,5-dihydroxybenzoic acid],
 - (iii) 4.9 mg trisodium citrate, anhydrous,
 - (iv) 0.37 mg citric acid, anhydrous, and
 - (v) 10.0 mg inositol.

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

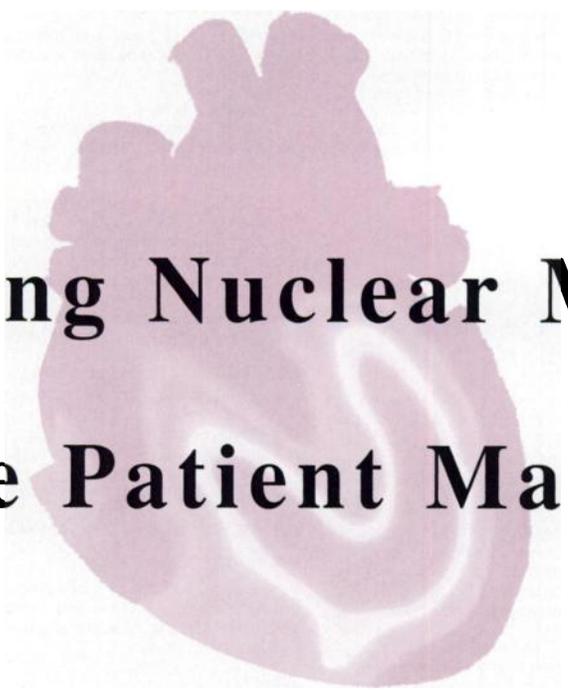
2. A 10-mL vial of Indium In-111 Chloride Sterile Solution, which contains 1.1 mL of 111 MBq/mL (3.0 mCi/mL) indium In-111 chloride in 0.02 N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 µg/mL (ferric ion, 1.2 µg/mL). The vial contents are sterile and nonpyrogenic.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

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

MALLINCKRODT

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

1. Teramani 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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Brief Summary

MYOVIEW™

Kit for the Preparation of Technetium Tc99m Tetrofosmin for injection

Diagnostic radiopharmaceutical For intravenous use only
Code N166A

DESCRIPTION

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

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

CLINICAL PHARMACOLOGY

General

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

Clinical Trials

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

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

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

PRECAUTIONS

General

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

The contents of the Myoview vial are intended only for use in the preparation of technetium

Tc99m tetrofosmin injection and are NOT to be administered directly to the patient.

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

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

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

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been conducted to evaluate carcinogenic potential or effects on fertility. Tetrofosmin sulphosalicylate was not mutagenic *in vitro* in the Ames test, mouse lymphoma, or human lymphocyte tests, nor was it clastogenic *in vivo* in the mouse micronucleus test.

Pregnancy Category C

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

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse events were evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 26-94 years). The subjects received a mean dose of 7.67 mCi on the first injection and 22.4 mCi on the second injection of Myoview.

Deaths did not occur during the clinical study period of 2 days. Six cardiac deaths occurred 3 days to 6 months after injection and were thought to be related to the underlying disease or cardiac surgery. After Myoview injection, serious episodes of angina occurred in 3 patients. Overall cardiac adverse events occurred in 5/764 (less than 1%) of patients after Myoview injection.

The following events were noted in less than 1% of patients:

Cardiovascular: angina, hypertension, Torsades de Pointes
Gastrointestinal: vomiting, abdominal discomfort
Hypersensitivity: cutaneous allergy, hypotension, dyspnea
Special Senses: metallic taste, burning of the mouth, smelling something

There was a low incidence (less than 4%) of a transient and clinically insignificant rise in white blood cell counts following administration of the agent.

DOSAGE AND ADMINISTRATION

For exercise and rest imaging, Myoview is administered in two doses:

- The first dose of 5-8 mCi (185-296 MBq) is given at peak exercise.
- The second dose of 15-24 mCi (555-888 MBq) is given approximately 4 hours later, at rest.

Imaging may begin 15 minutes following administration of the agent.

Dose adjustment has not been established in renally or liver impaired, pediatric or geriatric patients.

RADIATION DOSIMETRY

Based on human data, the absorbed radiation doses to an average human adult (70 kg) from intravenous injections of the agent under exercise and resting conditions are listed in Table 1. The values are listed in descending order as rad/mCi and µGy/MBq and assume urinary bladder emptying at 3.5 hours.

Table 1

Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

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

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

Manufactured by Amersham International plc – Amersham, United Kingdom
Patent No. 5,045,302 (r)

Distributed by:

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- White blood cell and platelet counts tend to return to pretreatment levels by week 8

*In controlled clinical trials, approximately half the patients reduced opioid usage by week 4.

Quadramet® causes bone marrow suppression. Prior to administration, clinical benefit should be judged to outweigh the risk in patients having compromised bone marrow reserves or undergoing therapy that causes myelosuppression.

Quadramet® 
Samarium Sm 153 Lexidronam Injection

Gets cancer bone pain at its source

Please see brief summary of prescribing information for Quadramet® on adjacent page.

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Therapeutic – For Intravenous Administration

INDICATIONS: Quadramet is indicated for relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on radionuclide bone scan.

CONTRAINDICATIONS: Quadramet is contraindicated in patients who have known hypersensitivity to EDTMP or similar phosphonate compounds.

WARNINGS: Quadramet causes bone marrow suppression. In clinical trials, white blood cell counts and platelet counts decreased to a nadir of approximately 40% to 50% of baseline in 123 (95%) of patients within 3 to 5 weeks after Quadramet, and tended to return to pretreatment levels by 8 weeks. The grade of marrow toxicity is shown in the table below.

Toxicity Grade*	Hemoglobin		Leucocytes		Platelets	
	Placebo N = 85	1.0 mCi/kg N = 185	Placebo N = 85	1.0 mCi/kg N = 184	Placebo N = 85	1.0 mCi/kg N = 185
0-2	78 (92%)	162 (88%)	85 (100%)	169 (92%)	85 (100%)	173 (94%)
3	6 (7%)	20 (11%)	0 (0%)	15 (8%)	0 (0%)	10 (5%)
4	1 (1%)	3 (2%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)

* Toxicity Grade based upon National Cancer Institute Criteria; normal levels are Hemoglobin >10g/dL, Leucocyte ≥4.0 x 10³/μL, and Platelets ≥150,000/μL.

Before Quadramet is administered, consideration should be given to the patient's current clinical and hematologic status and bone marrow response history to treatment with myelotoxic agents. Metastatic prostate and other cancers can be associated with disseminated intravascular coagulation (DIC); caution should be exercised in treating cancer patients whose platelet counts are falling or who have other clinical or laboratory findings suggesting DIC. Because of the unknown potential for additive effects on bone marrow, Quadramet should not be given concurrently with chemotherapy or external beam radiation therapy unless the clinical benefits outweigh the risks. Use of Quadramet in patients with evidence of compromised bone marrow reserve from previous therapy or disease involvement is not recommended unless the potential benefits of the treatment outweigh the risks. Blood counts should be monitored weekly for at least 8 weeks, or until recovery of adequate bone marrow function.

Pregnancy: As with other radiopharmaceutical drugs, Quadramet can cause fetal harm when administered to a pregnant woman. Adequate and well controlled studies have not been conducted in animals or pregnant women. Women of child-bearing age should have a negative pregnancy test before administration of Quadramet. If this drug is used during pregnancy, or if a patient becomes pregnant after taking this drug, the patient should be apprised of the potential hazard to the fetus. Women of child-bearing potential should be advised to avoid becoming pregnant soon after receiving Quadramet. Men and women patients should be advised to use an effective method of contraception after the administration of Quadramet.

PRECAUTIONS: EDTMP is a chelating agent. Although the chelating effects have not been evaluated thoroughly in humans, dogs that received non-radioactive samarium EDTMP (6 times the human dose based on body weight, 3 times based on surface area) developed a variety of electrocardiographic (ECG) changes (with or without the presence of hypocalcemia). The causal relationship between the hypocalcemia and ECG changes has not been studied. Whether Quadramet causes electrocardiographic changes or arrhythmias in humans has not been studied. Caution and appropriate monitoring should be given when administering Quadramet to patients (See Laboratory Tests).

Because concomitant hydration is recommended to promote the urinary excretion of Quadramet, appropriate monitoring and consideration of additional supportive treatment should be used in patients with a history of congestive heart failure or renal insufficiency.

This drug should be used with caution in patients with compromised bone marrow reserves. See Warnings.

Skeletal: Spinal cord compression frequently occurs in patients with known metastases to the cervical, thoracic or lumbar spine. In clinical studies of Quadramet, spinal cord compression was reported in 7% of patients who received placebo and in 8.3% of patients who received 1.0 mCi/kg Quadramet. Quadramet is not indicated for treatment of spinal cord compression. Quadramet administration for pain relief of metastatic bone cancer does not prevent the development of spinal cord compression. When there is a clinical suspicion of spinal cord compression, appropriate diagnostic and therapeutic measures must be taken immediately to avoid permanent disability.

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 government agency authorized to license the use of radionuclides.

Quadramet, like other radioactive drugs, must be handled with care, and appropriate safety measures must be taken to minimize radiation exposure of clinical personnel and others in the patient environment.

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. Urinary excretion of radioactivity occurs over about 12 hours (with 35% occurring during the first 6 hours). Studies have not been done on the use of Quadramet in patients with renal impairment.

PREGNANCY Pregnancy Category D. See Warnings Section.

NURSING MOTHERS It is not known whether Quadramet is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Quadramet, a decision should be made whether to continue nursing or to administer the drug. If Quadramet is administered, formula feedings should be substituted for breast feedings.

PEDIATRIC USE Safety and effectiveness in pediatric patients below the age of 16 years have not been established.

ADVERSE EVENTS

Adverse events were evaluated in a total of 580 patients who received Quadramet in clinical trials. Of the 580 patients, there were 472 men and 108 women with a mean age of 66 (range 20 to 87).

Of these patients, 472 (83%) had at least one adverse event. In a subgroup of 399 patients who received Quadramet 1.0 mCi/kg, there were 23 deaths and 46 serious adverse events. The deaths occurred an average of 67 days (9 to 130) after Quadramet. Serious events occurred an average of 46 days (1 - 118) after Quadramet. Although most of the patient deaths and serious adverse events appear to be related to the underlying disease, the relationship of end stage disease, marrow invasion by cancer cells, previous myelotoxic treatment and Quadramet toxicity can not be easily distinguished. In clinical studies, two patients with rapidly progressive prostate cancer developed thrombocytopenia and died 4 weeks after receiving Quadramet. One of the patients showed evidence of disseminated intravascular coagulation (DIC); the other patient experienced a fatal cerebrovascular accident, with a suspicion of DIC. The relationship of the DIC to the bone marrow suppressive effect of Samarium is not known. Marrow toxicity occurred in 277 (47%) patients (See Warnings section).

In controlled studies, 7% of patients receiving 1.0 mCi/kg Quadramet (as compared to 6% of patients receiving placebo) reported a transient increase in bone pain shortly after injection (flare reaction). This was usually mild, self-limiting, and responded to analgesics.

Selected adverse events reported in ≥ 1.0% of people who received Quadramet or placebo in controlled clinical trials

ADVERSE EVENT	Placebo N = 90	Quadramet 1.0 mCi/kg N = 199
# Patients with Any Adverse Event	72 (80%)	169 (85%)
Body As A Whole	56 (62%)	100 (50%)
Pain Flare Reaction	5 (5.6%)	14 (7.0%)
Cardiovascular	19 (21%)	32 (16%)
Arrhythmias	2 (2.2%)	10 (5.0%)
Chest Pain	4 (4.4%)	8 (4.0%)
Hypertension	0	6 (3.0%)
Hypotension	2 (2.2%)	4 (2.0%)
Digestive	44 (49%)	82 (41%)
Abdominal Pain	7 (7.8%)	12 (6.0%)
Diarrhea	3 (3.3%)	12 (6.0%)
Nausea &/or Vomiting	37 (41.1%)	65 (32.7%)
Hematologic & Lymphatic	12 (13%)	54 (27%)
Coagulation Disorder	0	3 (1.5%)
Hemoglobin Decreased	21 (23.3%)	81 (40.7%)
Leukopenia	6 (6.7%)	118 (59.3%)
Lymphadenopathy	0	4 (2.0%)
Thrombocytopenia	8 (8.9%)	138 (69.3%)
Any Bleeding Manifestations*	8 (8.9%)	32 (16.1%)
Ecchymosis	1 (1.1%)	3 (3.0%)
Epistaxis	1 (1.1%)	4 (2.0%)
Hematuria	3 (3.3%)	10 (5%)
Infection	10 (11.1%)	34 (17.1%)
Fever and/or Chills	10 (11.1%)	17 (8.5%)
Infection, Not Specified	4 (4.4%)	14 (7.0%)
Oral Moniliasis	1 (1.1%)	4 (2.0%)
Pneumonia	1 (1.1%)	3 (1.5%)
Musculoskeletal	28 (31%)	55 (27%)
Myasthenia	8 (8.9%)	13 (6.5%)
Pathologic Fracture	2 (2.2%)	5 (2.5%)
Nervous	39 (43%)	59 (30%)
Dizziness	1 (1.1%)	8 (4.0%)
Paresthesia	7 (7.8%)	4 (2.0%)
Spinal Cord Compression	5 (5.5%)	13 (6.5%)
Cerebrovascular Accident/Stroke	0	2 (1.0%)
Respiratory	24 (27%)	35 (18%)
Bronchitis/Cough Increased	2 (2.2%)	8 (4.0%)
Special Senses	11 (12%)	11 (6%)
Skin & Appendages	17 (19%)	13 (7%)
Purpura	0	2 (1%)
Rash	2 (2.2%)	2 (1%)

*Includes hemorrhage (gastrointestinal, ocular) reported in <1%.

In an additional 200 patients who received Quadramet in uncontrolled clinical trials, adverse events that were reported at a rate of ≥1.0% were similar except for 9 (4.5%) patients who had agranulocytosis. Other selected adverse events that were reported in <1% of the patients who received Quadramet 1.0 mCi/kg in any clinical trial include: alopecia, angina, congestive heart failure, sinus bradycardia, and vasodilation.

OVERDOSAGE: Overdosage with Quadramet has not been reported. An antidote for Quadramet overdosage is not known. The anticipated complications of overdosage would likely be secondary to bone marrow suppression from the radioactivity of ¹⁵³Sm, or secondary to hypocalcemia and cardiac arrhythmias related to the EDTMP.

DOSE AND ADMINISTRATION: The recommended dose of Quadramet is 1.0 mCi/kg, administered intravenously over a period of one minute through a secure in-dwelling catheter and followed with a saline flush. Dose adjustment in patients at the extremes of weight have not been studied. Caution should be exercised when determining the dose in very thin or very obese patients.

The dose should be measured by a suitable radioactivity calibration system, such as a radioisotope dose calibrator, immediately before administration.

The dose of radioactivity to be administered and the patient should be verified before administering Quadramet. Patients should not be released until their radioactivity levels and exposure rates comply with federal and local regulations.

The patient should ingest (or receive by i.v. administration) a minimum of 500 mL (2 cups) of fluids prior to injection and should void as often as possible after injection to minimize radiation exposure to the bladder.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. The solution should not be used if it is cloudy or if it contains particulate matter. Quadramet contains calcium and may be incompatible with solutions that contain molecules that can complex with and form calcium precipitates.

Quadramet should not be diluted or mixed with other solutions.

Thaw at room temperature before administration and use within 8 hours of thawing.



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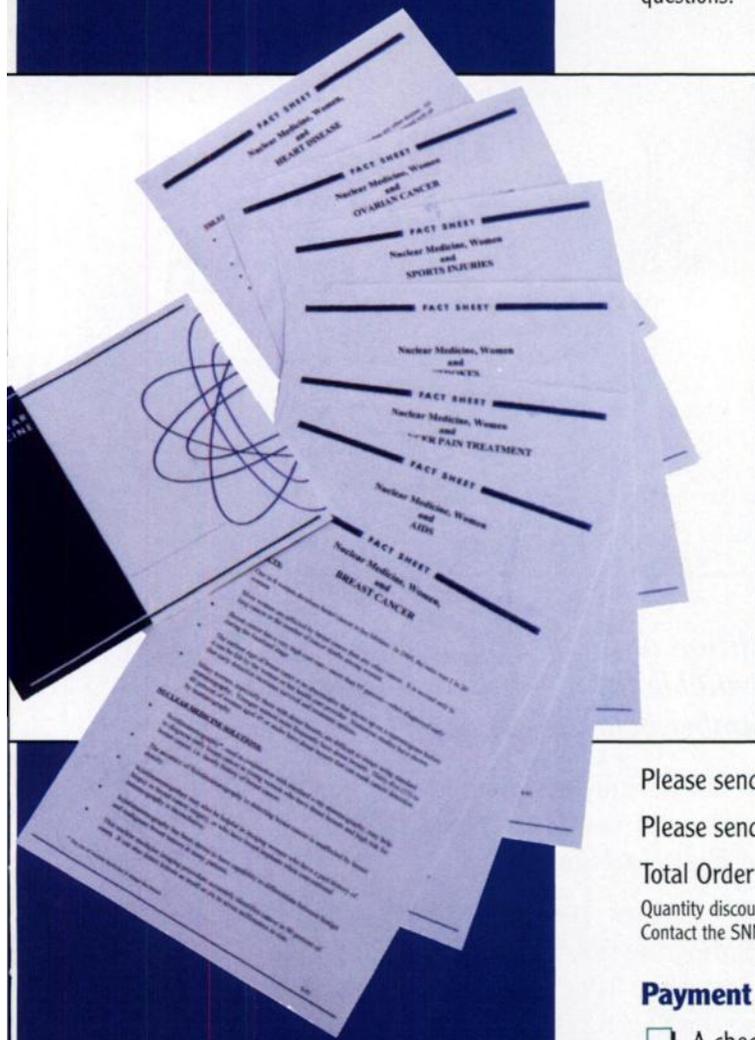
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Now Available From the Society of Nuclear Medicine

Women's Health Information Kit

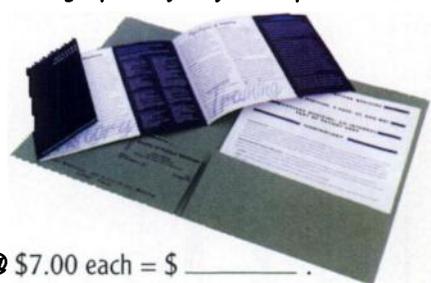
This kit provides topical information on current women's health issues and appropriate nuclear medicine solutions as well as background and historical information about nuclear medicine. Each fact sheet contains the latest facts about a specific health issue and the ways in which nuclear medicine provides a diagnostic and sometimes therapeutic tool.

The Nuclear Medicine Women's Health Information Kit is a valuable tool to promote nuclear medicine and your hospital to physicians, patients, and the general public. Don't lose another day wondering how you can increase referrals to your department or how to educate women about how nuclear medicine can provide answers to some of their most pressing health questions.



Here are Some Ways You Can Use the Information Kit:

- * Encourage department heads to use the SNM fact sheets in peer-to-peer communications with referring physicians
- * Send physicians who refer to nuclear medicine packets of the SNM fact sheets for distribution to their patients
- * Display SNM fact sheets in Nuclear Medicine department waiting rooms
- * Distribute the fact sheets at health fairs where hospital services are promoted
- * Include the information in your hospital's community newsletter
- * Serve as a news pitch to local media to get publicity for your hospital and its nuclear medicine department
- * Use as the basis for a SNM Chapter "Public Awareness" Educational Symposium



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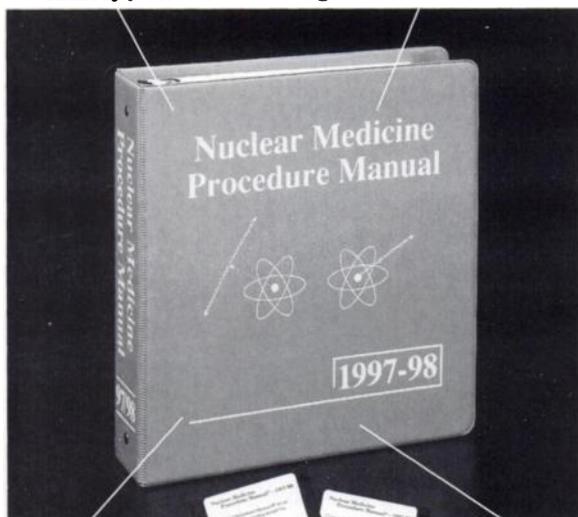
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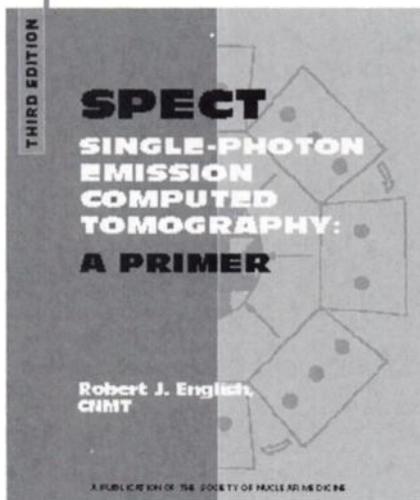
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In evaluating patients with kidney and urinary tract disease, nuclear medicine techniques fill a valuable role, but consensus on procedures and protocols has sometimes been hard to find.

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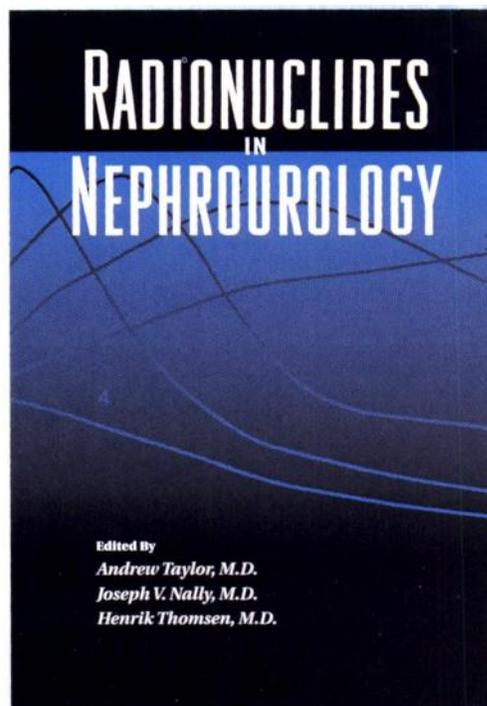
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NEW AND NOTABLE FROM THE SOCIETY OF NUCLEAR MEDICINE MIRDO COMMITTEE...

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

MIRD CELLULAR S VALUES

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

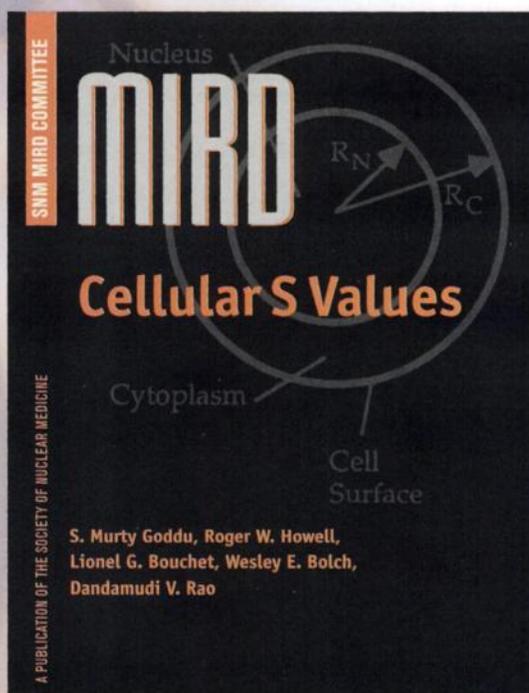
MIRD Cellular S Values provides nuclear medicine facilities the data necessary in estimating absorbed dose at the cellular level from intracellularly localized radionuclides using cellular S values for emitters of monoenergetic electrons and alpha particles.

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

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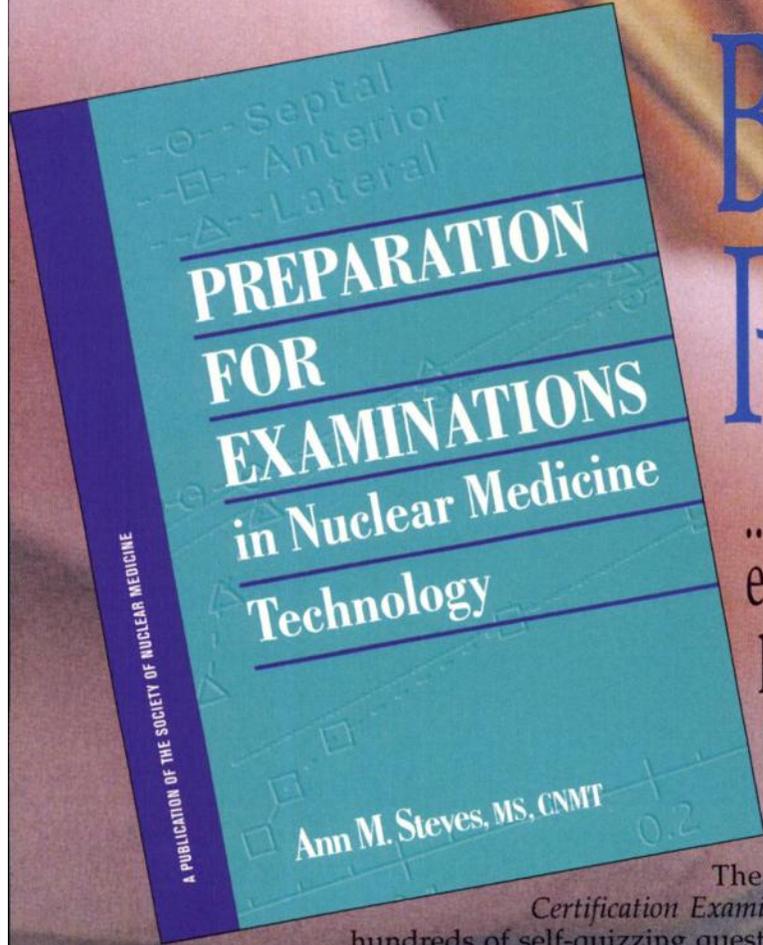
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The *MIRD Primer* is unquestionably the standard reference on absorbed dosage of radiopharmaceuticals in human beings, offering a thorough review of absorbed dose calculations used in the application of radiopharmaceuticals to medical studies. Included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

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

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Nuclear Medicine Residency

St. Lukes-Roosevelt Hospital Center, a 1315 bed voluntary university hospital of Columbia University College of Physicians and Surgeons, is offering a two-year nuclear medicine residency position beginning in July, 1998 consisting of concurrent training in clinical imaging, physics, radiopharmacy and radio-immunoassay. The program is designed to prepare trainees for examination and certification by the American Board of Nuclear Medicine. The Nuclear Medicine Service, a division of the Department of Radiology, is equipped with 16 state-of-the-art camera/computer systems, housed in laboratories for which new construction/renovation is nearly complete. A full spectrum of nuclear medicine and nuclear cardiology studies are performed. Research involves both

clinical and basis sciences. Training programs include radiology and nuclear medicine residencies and a nuclear cardiology fellowship. A letter of inquiry should be sent to: Steven Parmett, MD, Roosevelt Hospital Site Director, Division of Nuclear Medicine, St. Lukes-Roosevelt Hospital, 1000 Tenth Amsterdam Ave., New York, NY 10019. SLRHC is an Equal Opportunity Employer.

Nuclear Medicine Residence/Fellowship

The Harvard Medical School, Joint Program in Nuclear Medicine, invites applications to the two-year residency and one-year fellowship programs that begin July, 1998. Please direct your inquiries to: Kathy Fantegrossi, Program Coordinator, Joint Program in Nuclear Medicine, Childrens Hospital, 300 Longwood Ave., Boston, MA 02115 or by phone at (617) 355-4004.

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Research fellowship in PET at the Northern California PET Imaging Center affiliated with the University of California, Davis, for one year starting 7/1/98. A leading clinical and research facility, 800 studies per year in oncology, neurology and cardiology. BC/BE applicant expected to participate in interpretation of studies, oncologic PET research and presentation of results and teaching. Please send curriculum vitae to: Peter E. Valk, MD, Northern California PET Imaging Center, 3195 Folsom Blvd., Sacramento, CA 95816.

Position Wanted

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Chair, Institute of Nuclear Medicine

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The Institute of Nuclear Medicine at Soroka requires a leader to navigate and successfully develop it through this forthcoming phase of rapid growth. We seek to appoint to the position of Chair of the Institute of Nuclear Medicine an experienced clinician that has made significant contributions to the field of nuclear medicine. Applicants must be specialists or Boards Certified in nuclear medicine, and will be expected to provide leadership in teaching and research in clinical nuclear medicine. A conjoint teaching appointment at the Health Sciences Faculty of the Ben Gurion University of the Negev will be offered to the successful applicant.

For further information please contact:

Julian Zelingher M.D.
VP, Soroka Medical Center
PO Box 151
Beer Sheva 84101, Israel
Phone: 97276403408
Facsimile: 97276277364
email: ilanz@bgumail.bgu.ac.il



Applications should be made in writing and mailed to the above mentioned address. Applications should include a letter of interest, a detailed curriculum vitae, evidence of medical licensure and specialization and names, addresses and contact numbers of three referees.

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James M. Mountz, MD, PhD, Director of Neuro-Nuclear Imaging, Division of Nuclear Medicine, Department of Radiology, The University of Alabama at Birmingham, 619 South 19th Street, Birmingham, AL 35233-6835. Phone: (205) 975-8336, Fax: (205) 934-5589, E-Mail: medy010@uabdp.dpo.uab.edu.
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MAYO CLINIC SCOTTSDALE



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Mayo Clinic Scottsdale will be using a computerized database beginning in 1998. Resumes will be accepted on a continuous basis for all positions. Individuals interested in future opportunities are encouraged to send a scannable resume to Human Resources. Specific skills and education (i.e., RN, BSN, Word, Excel, PowerPoint) should be listed. For best results, please use a standard typeface (10-14 points recommended) and avoid using graphics and dark colored paper.

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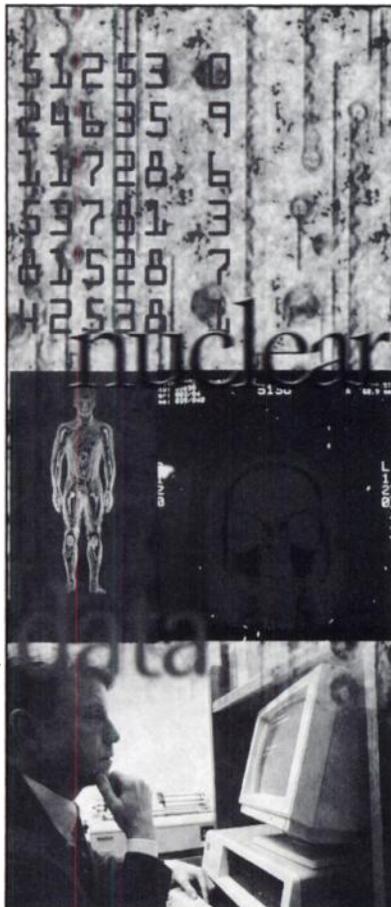
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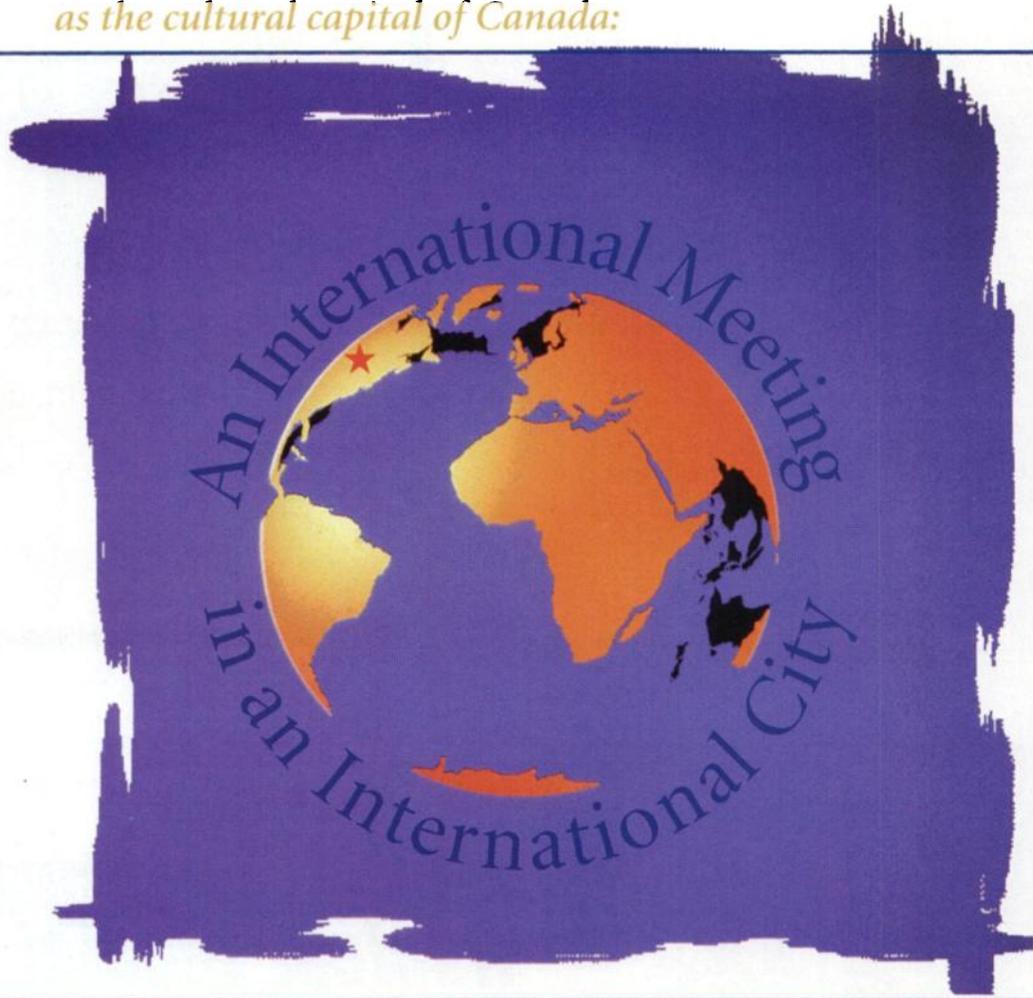
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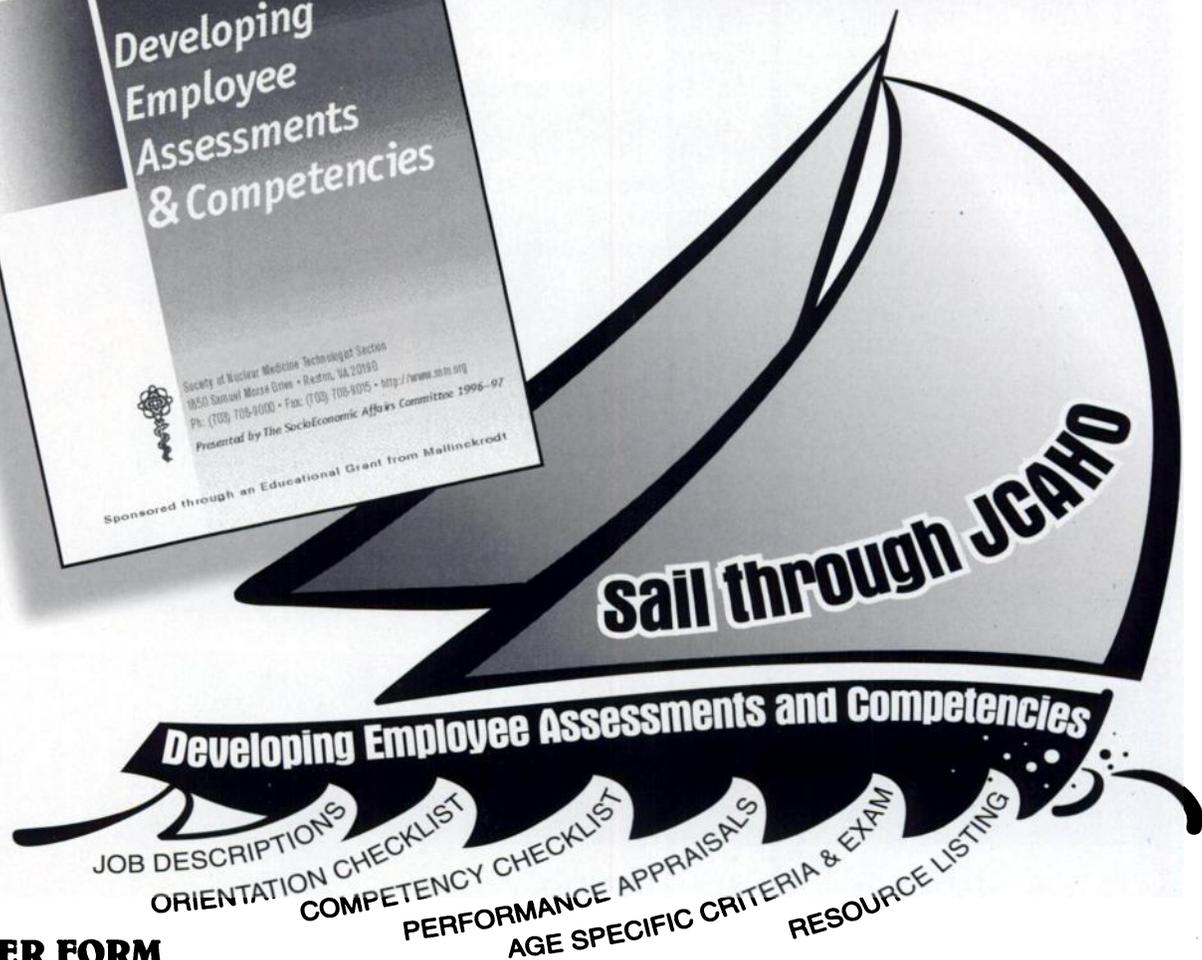
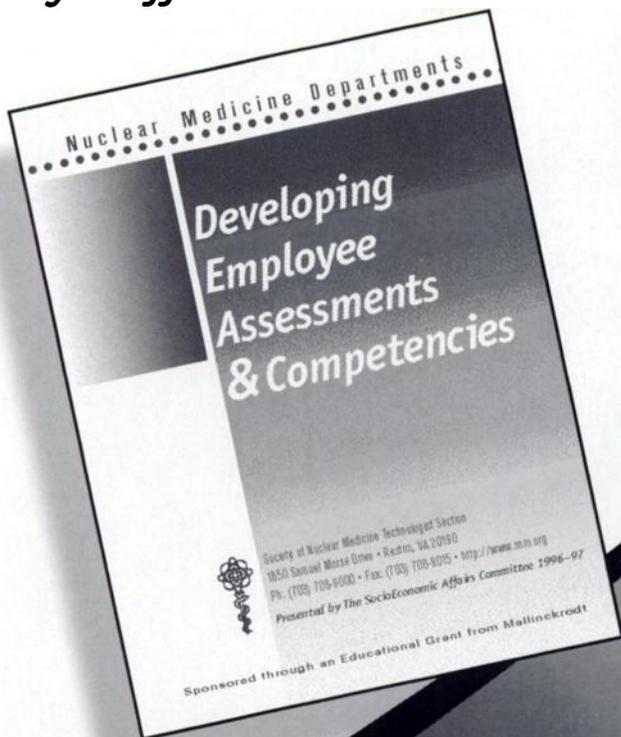
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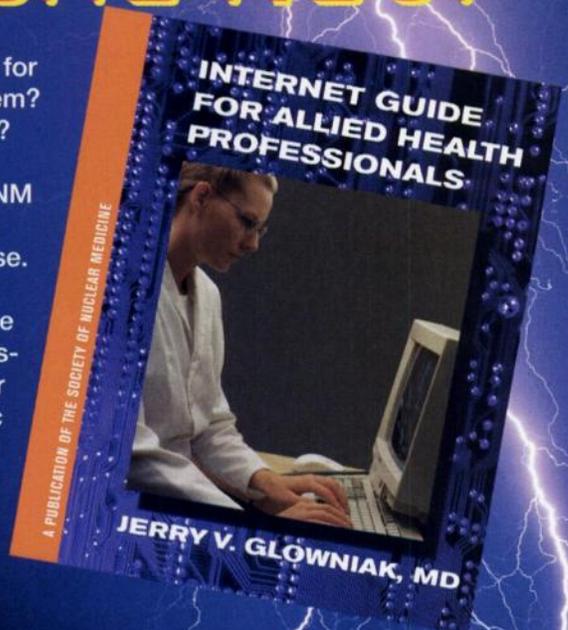
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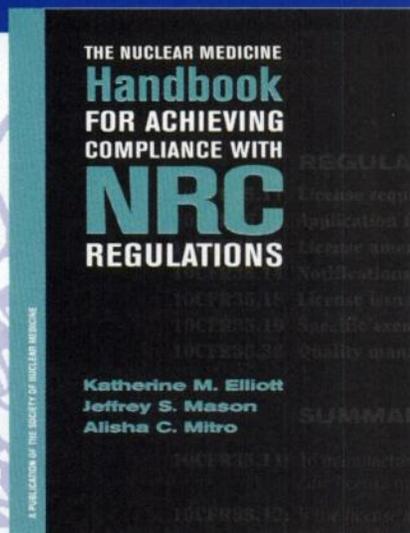


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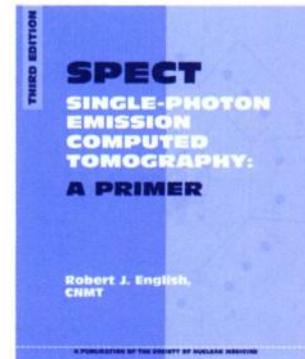
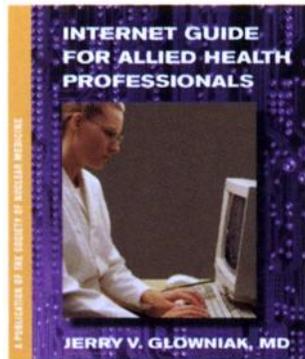
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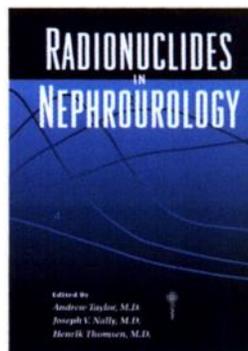
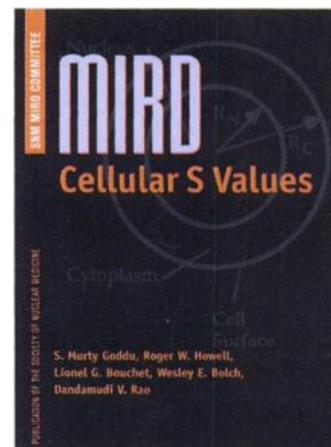
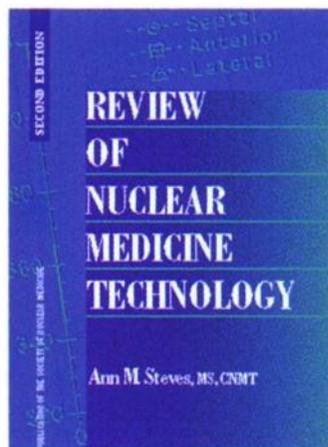
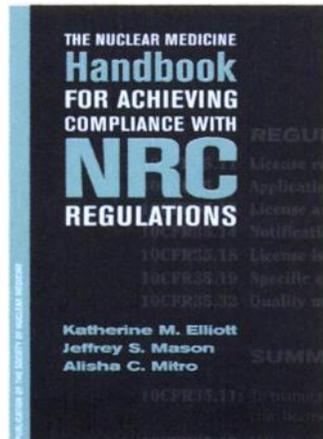
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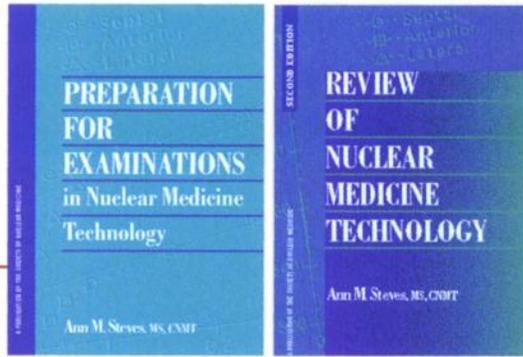
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Review, softcover, 141 pp., 1996, \$42 (\$30 SNM member).
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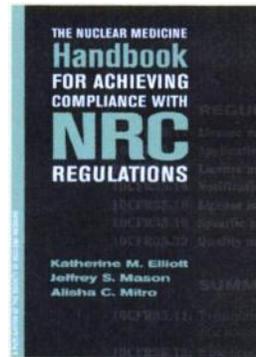
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Naomi P. Alazraki and Andrew T. Taylor, Jr., Emory University School of Medicine

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Katherine M. Elliott, Jeffrey S. Mason and Alisha C. Mitro, Office of Radiation Safety, Indiana University School of Medicine

Softcover, 162 pp., 1997, \$35 (\$25 SNM member). [ISBN 0-932004-50-4]

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New! Practical Mathematics in Nuclear Medicine Technology

Patricia Wells, University of Medicine and Dentistry of New Jersey and Martha Pickett, University of Arkansas Medical Science

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Curriculum Guide for Nuclear Medicine Technologists, second edition

Wanda M. Mundy and Gregory Passmore, Medical College of Georgia

Softcover, 86 pp., 1993, \$13.95 (Bulk quantities of 5 or more, \$9.95 each). [ISBN 0-932004-42-3]

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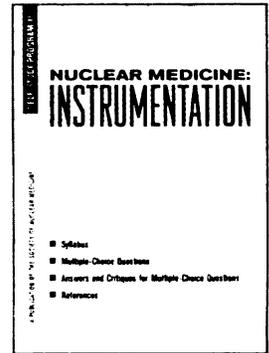
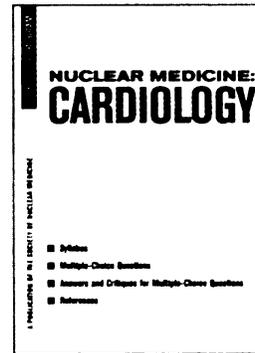
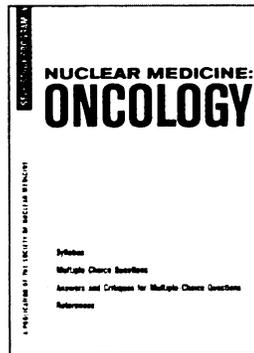
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Barry A. Siegel, Mallinckrodt Institute of Radiology and Peter T. Kirchner, University of Iowa Hospital and Clinics, Senior Editors



Softcover, 2 vols., 271 pp., 1988, \$105 (\$75 SNM member); (\$75 residents/technologists, with documentation). [ISBN 0-932004-30-X; 0-932004-33-4]

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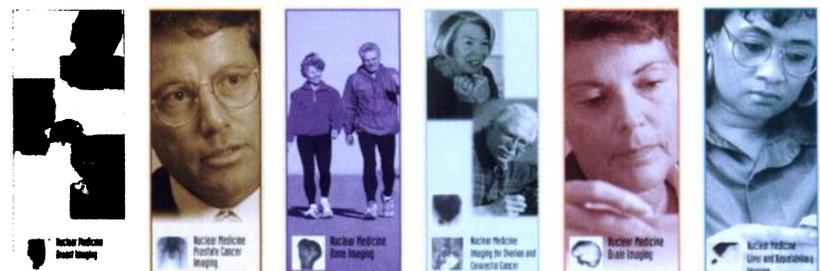
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Robert J. English, Brockton-West Roxbury VA Medical Center

Softcover, 223 pp., 1996, \$42 (\$30 SNM members). [ISBN 0-932004-43-1]

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Jerry V. Glowniak, Biomedical Information Communication Center, Oregon Health Sciences University

Softcover, 94 pp., 1997, \$28 (\$20 SNM member). [ISBN 0-932004-47-4]

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Kai Lee, Department of Radiology, USC Medical School
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Hardcover, 86 pp., 1992, \$49 (\$35 SNM member). [ISBN 0-932004-40-7]

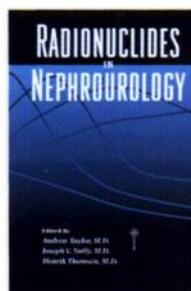
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Andrew T. Taylor, Jr., Joseph V. Nally and Henrik Thomsen, Editors

Softcover, 222 pp., 1997, \$50. [ISBN 0-932004-48-2]

Contributions from an international panel of experts highlight state-of-the-art applications of nuclear medicine in nephrology and urology.

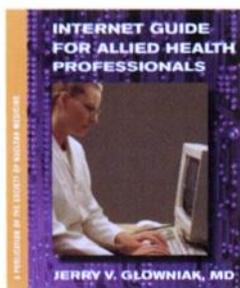
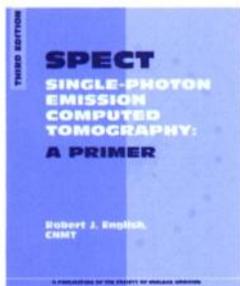
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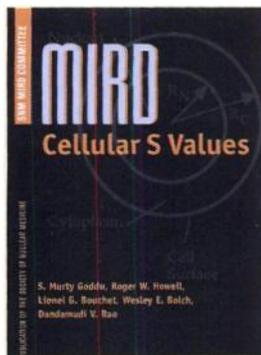
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S. Murty Goddu, Roger W. Howell, Lionel G. Bouchet, Wesley E. Bolch and Dandamudi Rao, SNM MIRD Committee

Hardcover, 183 pp., 1997, \$63 (\$45 SNM member). [ISBN 0-932004-46-6]

Provides tools necessary to estimate the absorbed dose at the cellular level from

intracellularly localized radionuclides using cellular S values for emitters of monoenergetic electrons and alpha particles, and radionuclides listed in *Radionuclide Data and Decay Schemes*. Cellular absorbed-dose estimates play an important role in evaluating the relative merits of different radionuclides and radiopharmaceuticals in improving the overall safety and efficacy of diagnostic and therapeutic nuclear medicine.

MIRD Primer for Absorbed Dose Calculations (Revised Edition)

Prepared by Robert Loevinger, Center for Radiation Research, National Bureau of Statistics; Thomas F. Budinger, Donner Laboratory; and Evelyn E. Watson, Oak Ridge Associated Universities

Hardcover, 128 pp., 1991, \$49 (\$35 SNM member). [ISBN 0-932004-38-5]

MIRD Radionuclide Data and Decay Schemes

David A. Weber, University of California, Davis; Keith F. Eckerman, Oak Ridge National Laboratory; L. Thomas Dillman, Ohio Wesleyan University and Jeffrey C. Ryman, Oak Ridge National Laboratory

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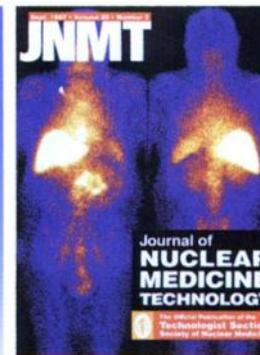
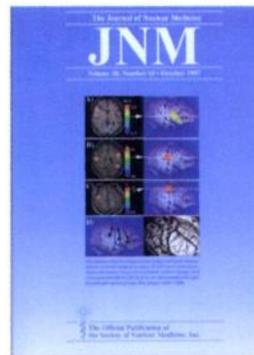
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CALL FOR TEACHING CASE STUDIES

The Society of Nuclear Medicine is embarking on a multi-year program to enhance the quality of nuclear medicine practice by providing a physician self-assessment program.

The Society is calling upon our membership to submit case studies to be considered by the Practice Management Committee for inclusion in SNM PEP. Cases will be assessed by physicians with varied levels of nuclear medicine practice.

The Physician Evaluation Program (SNM PEP) will target full and part-time nuclear medicine physicians as well as referring physicians such as radiologists, cardiologists, oncologists, and endocrinologists. Participating physicians will dictate a report after review and interpretation of each patient case and receive educational feedback on areas of weakness for each case module scored. Phase one of the program will include five nuclear medicine modules covering cardiovascular, bone, lung, thyroid and scintimammography procedures.

We ask that each case contain 2-5 images which may be submitted as original film or original digital (preferred). In addition, you should submit the real patient history, patient scan time and any other pertinent information, correlative imaging if available, and a copy of the final report in a separate word processing file.

Upon *acceptance* of each complete case for utilization in an SNM PEP module you will receive a **\$100.00 honorarium**. Unfortunately, no honoraria will be awarded for cases submitted but not chosen for utilization. The decision for acceptance by the Practice Management Committee will be final.

If your program is interested in learning more about this exciting opportunity to submit case studies, please contact Wendy Smith, Director of Health Care Policy, at the SNM headquarters office at 703-708-9000, ext. 242.

Society of Nuclear Medicine 45TH ANNUAL MEETING *Critical Dates*

Item	Due Date
PRE-REGISTRATION FORM. February Issue of JNM Important change	4/30/98
HOUSING FORM. February Issue of JNM	5/6/98

DON'T FORGET THE MID-WINTER MEETING IN LAS VEGAS, NEVADA

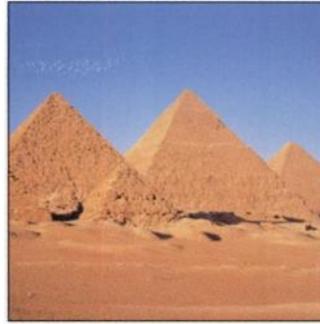
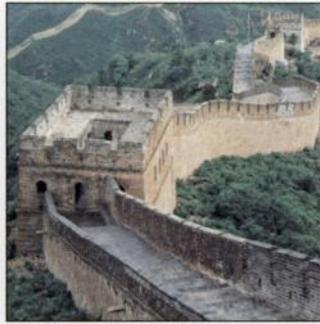
DATE: January 24 – February 3, 1998

LOCATION: The Alexis Park Resort

EDUCATION PROGRAM SPONSOR: The Computer and Instrumentation Council

For the most current meeting information, please visit our web site at www.snm.org

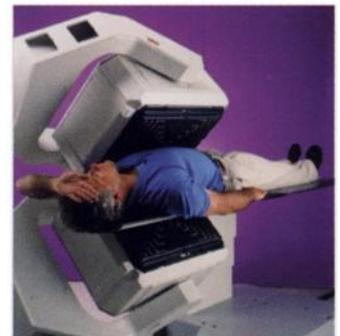
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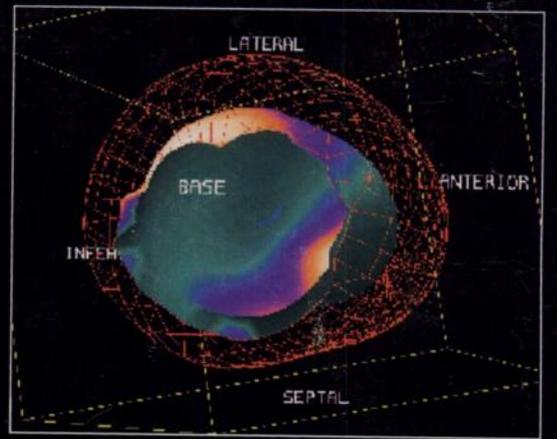
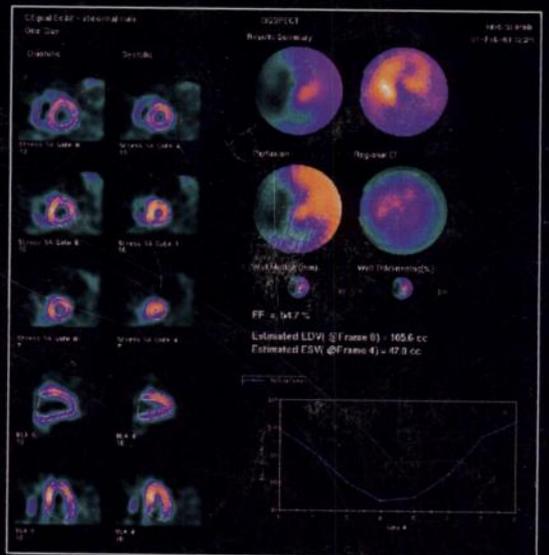
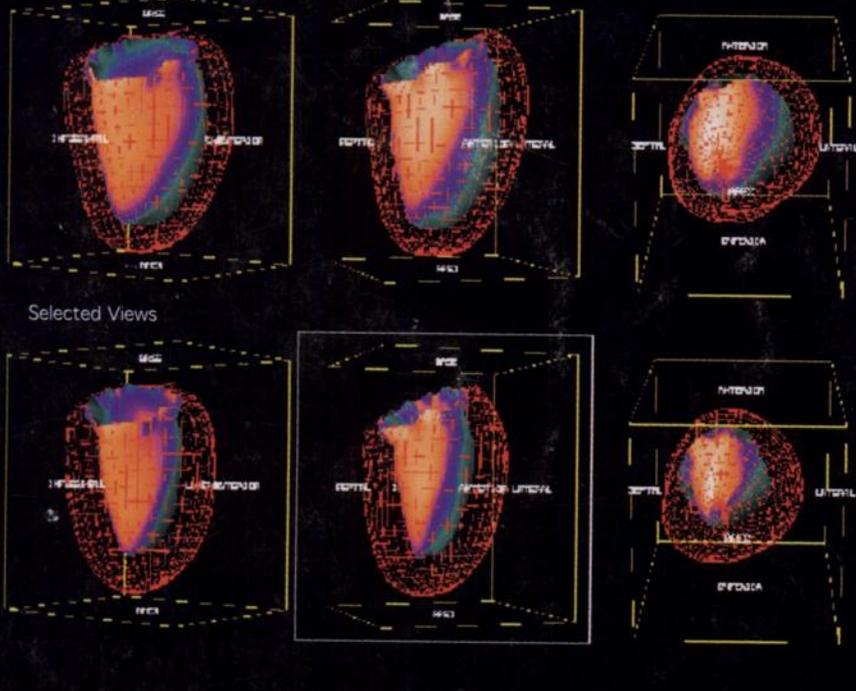
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