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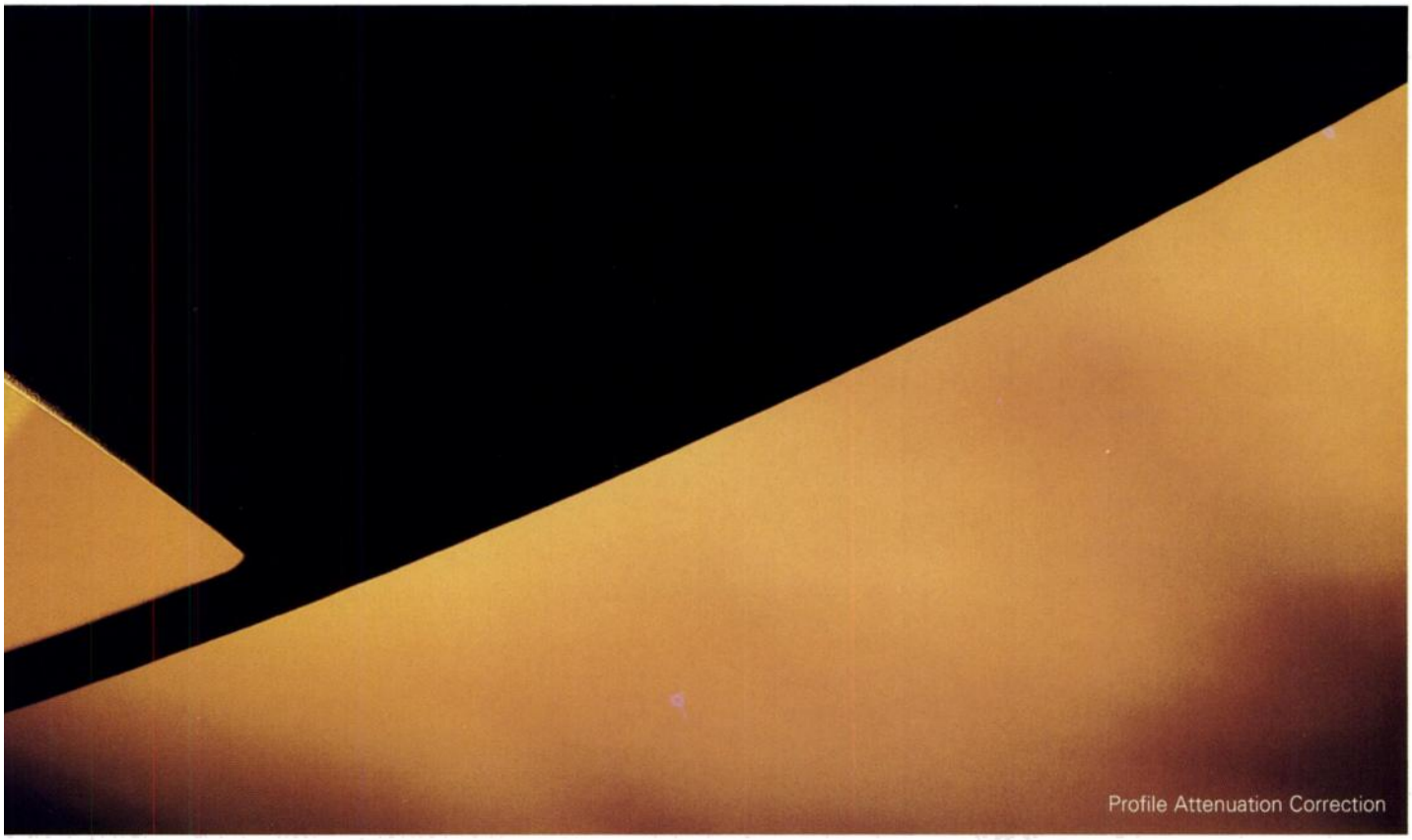
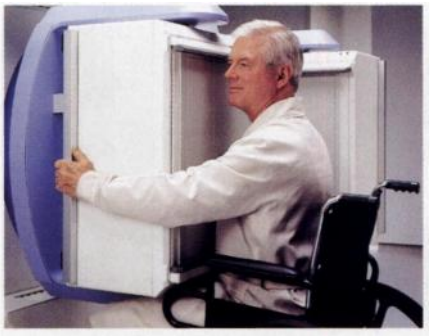
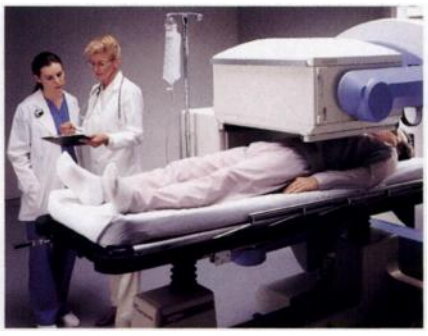


Easy patient access



E.CAM detectors with dual external rotation



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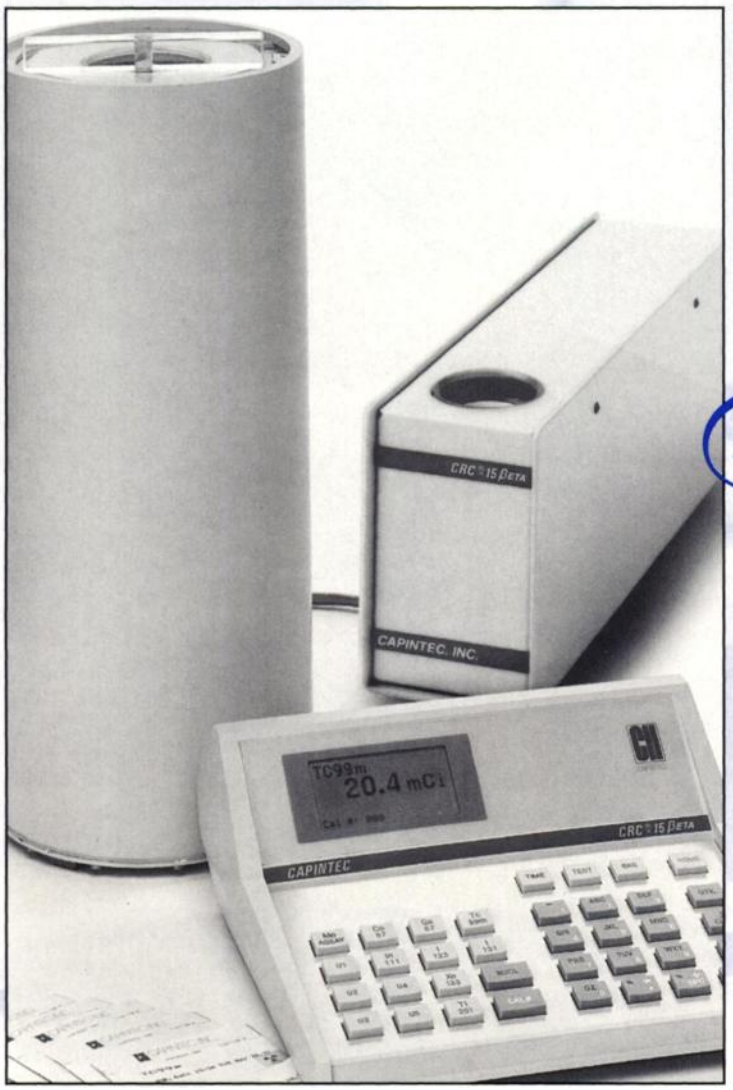

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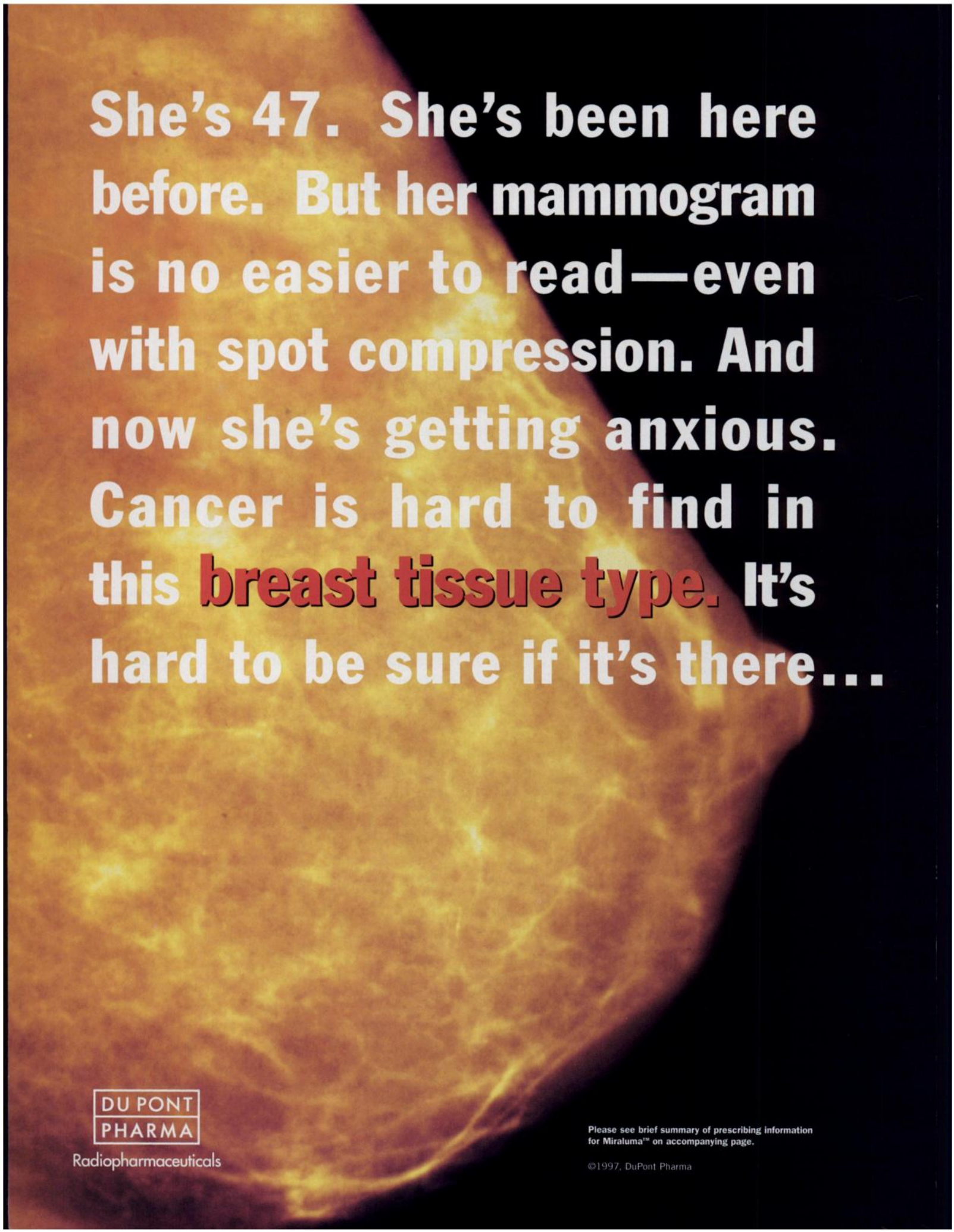
She's 47. She's been here before. But her mammogram is no easier to read—even with spot compression. And now she's getting anxious. Cancer is hard to find in this breast tissue type. It's hard to be sure if it's there...
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Radiopharmaceuticals
Please see brief summary of prescribing information for Miraluma™ on accompanying page.
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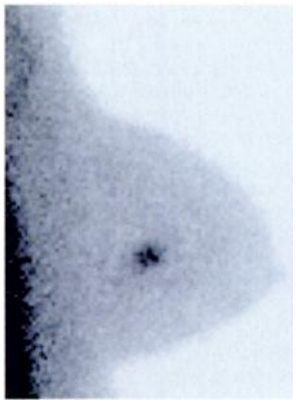

Right lateral view, biopsy-confirmed infiltrating ductal carcinoma

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Kit for the preparation of
Technetium Tc 99m Sestamibi

The next step toward an answer

miraluma™

Kit for the preparation of
Technetium Tc 99m Sestamibi

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 uticaria. 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, $Cu(MIBI)_4BF_4$, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all *in vitro*). At cytotoxic concentrations (≥ 20 µg/ml), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $Cu(MIBI)_4BF_4$ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg, > 600 × 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	Women	Men	Total
	n = 673	n = 685	n = 2361	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 ≤0.5% of patients: signs and symptoms consistent with seizure occurring shortly after administration of the agent ; transient arthritis; angioedema, arrythmia, 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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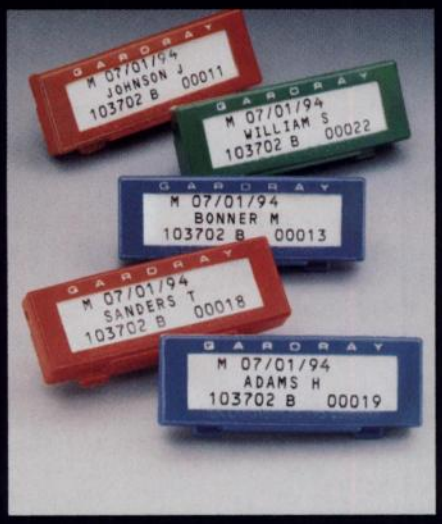

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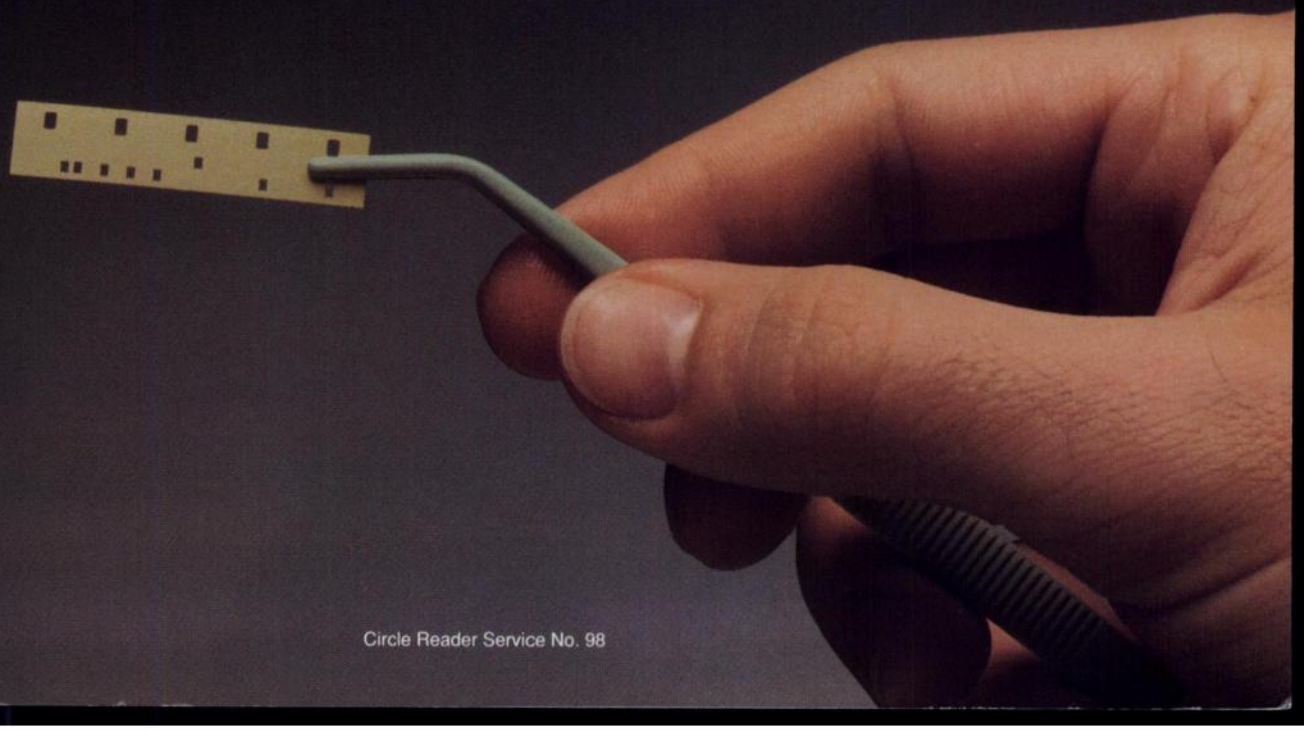

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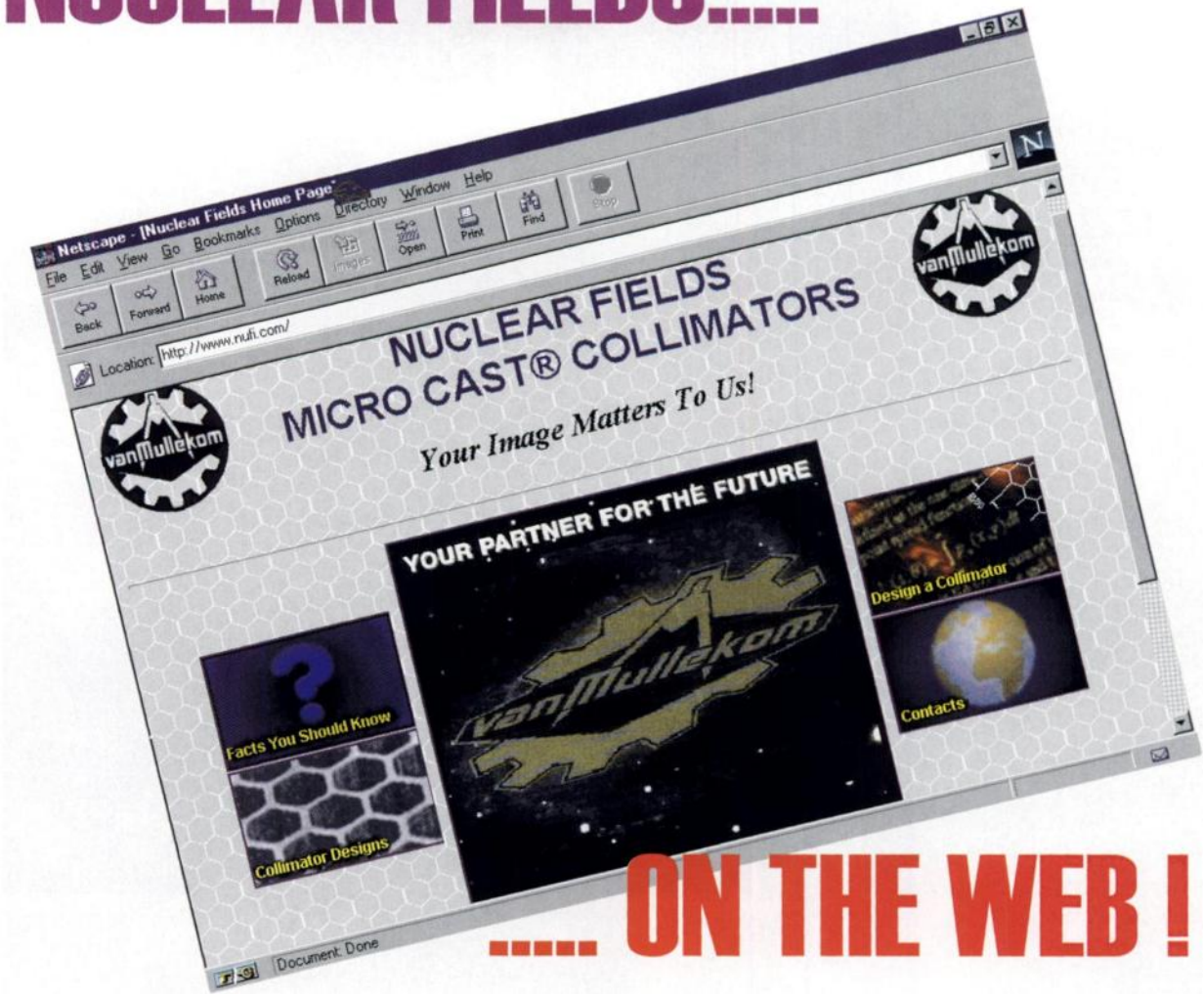

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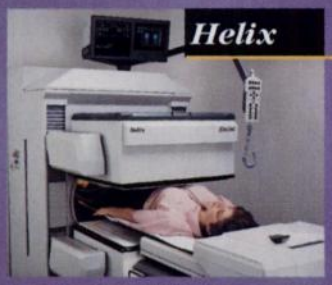

Dual-head multi-purpose, Slip-Ring integrated digital gamma camera

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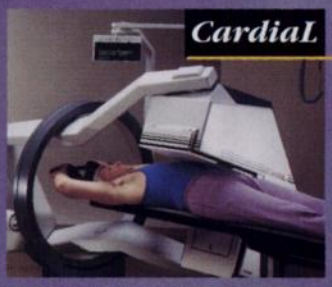
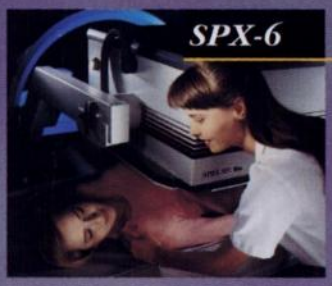


Bi-plane right-angle, cardiac-all-purpose integrated digital camera

SPX-6



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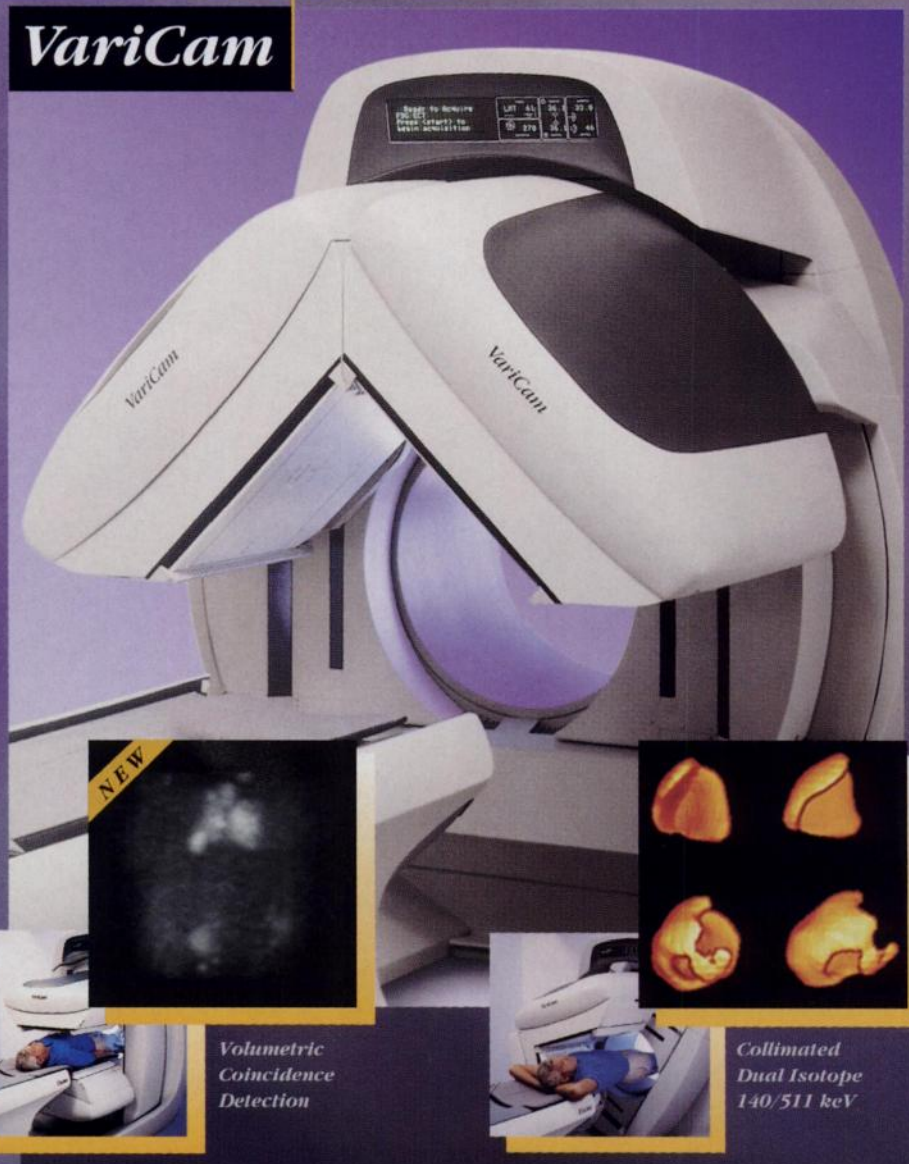

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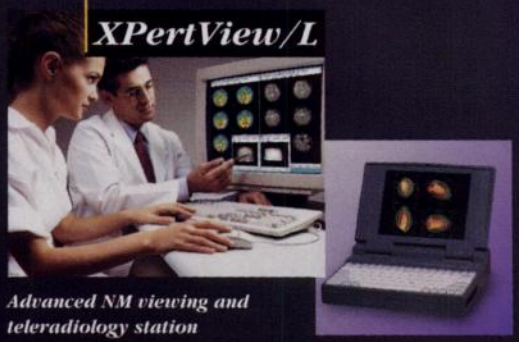

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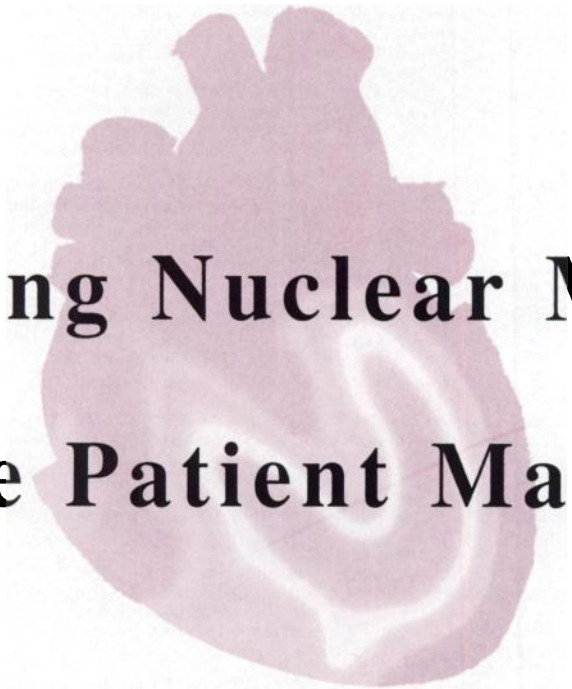

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Brief Summary

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-dioxa-6,9-diphospha-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-gluconate, and 1.8 mg sodium hydrogen carbonate. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

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

CLINICAL PHARMACOLOGY

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

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

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

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

PRECAUTIONS

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

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

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

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

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

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

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

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

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

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

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

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse events were evaluated in clinical trials of 764 adults (511 men and 253 women) with a mean age of 58.7 years (range 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 Absorted Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

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

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

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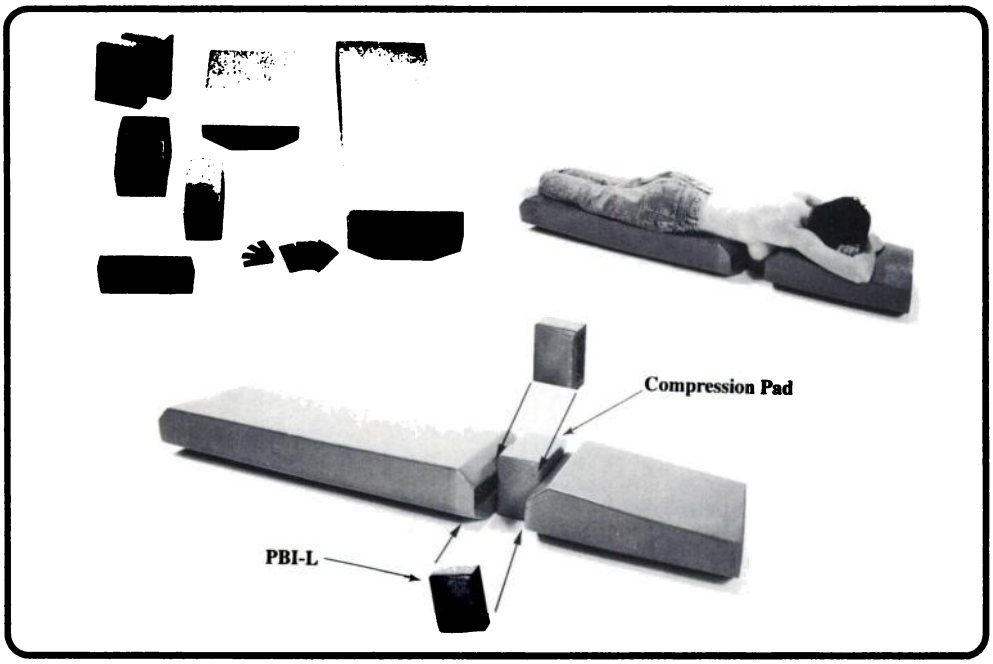

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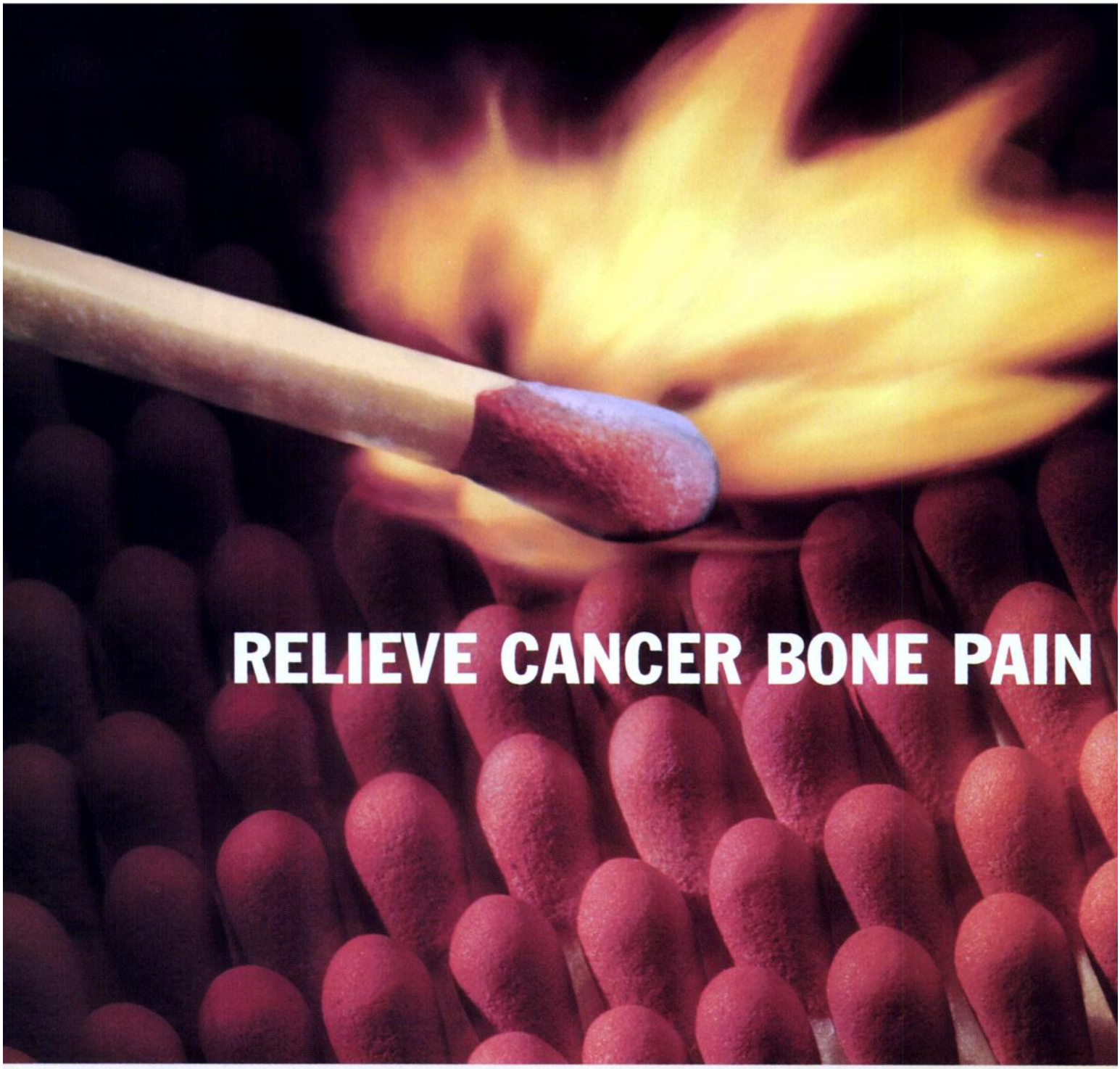

Now for osteoblastic metastases in patients with prostate or breast cancer

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

Relief

- Onset of pain relief as early as 1 week in the majority of patients
- Allows reduction in opioid use*

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

Recovery

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

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.

NEW

Quadramet®

Samarium Sm 153 Lexidronam Injection

Gets cancer bone pain at its source

Quadramet®

Samarium Sm 153 Lexidronam Injection

513145-0297 Brief Summary

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.

Number and percent of patients who experienced marrow toxicity in clinical trials of Quadramet

	Hemoglobin		Leucocytes		Platelets	
Toxicity Grade*	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 10^3/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.

The most common adverse events observed in controlled clinical studies of Quadramet, are given in the table below...

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 ^{153}Sm, or secondary to hypocalcemia and cardiac arrhythmias related to the EDTMP.

DOSAGE 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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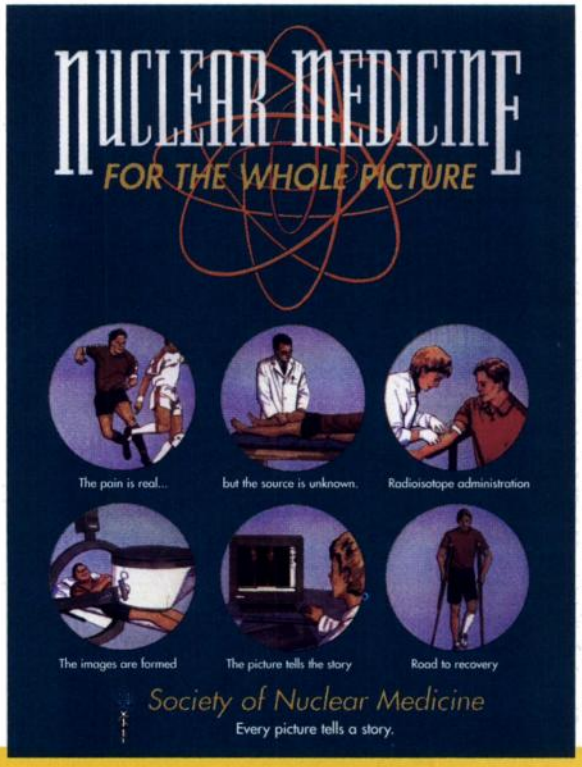

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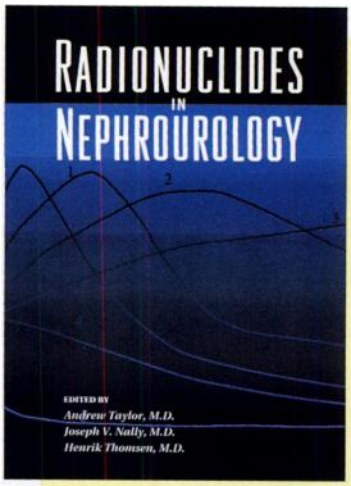

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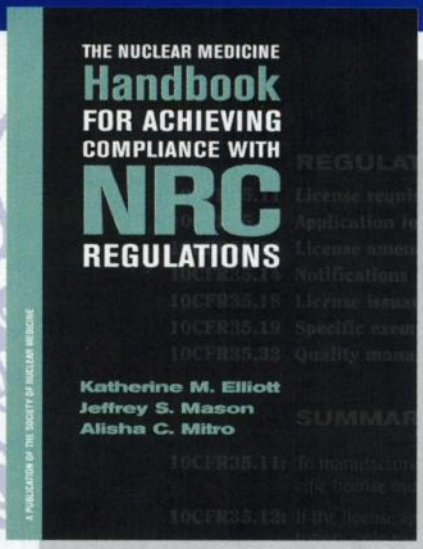

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To order, simply contact SNM's book distributor, Matthews Medical Books, at their toll-free number

1-800-633-2665 (non-U.S. 314-432-1401, or Fax: 314-432-7044).

*The Handbook is not a substitute for any regulation or license condition and is not endorsed by the Nuclear Regulatory Commission.

CALL FOR APPLICANTS

For the position of Editor in Chief,
The Journal of Nuclear Medicine

Term: January 1999 - December 2003
Transition begins: July 1998

Application deadline: November 1, 1997

To request application materials,
or for further information, please contact
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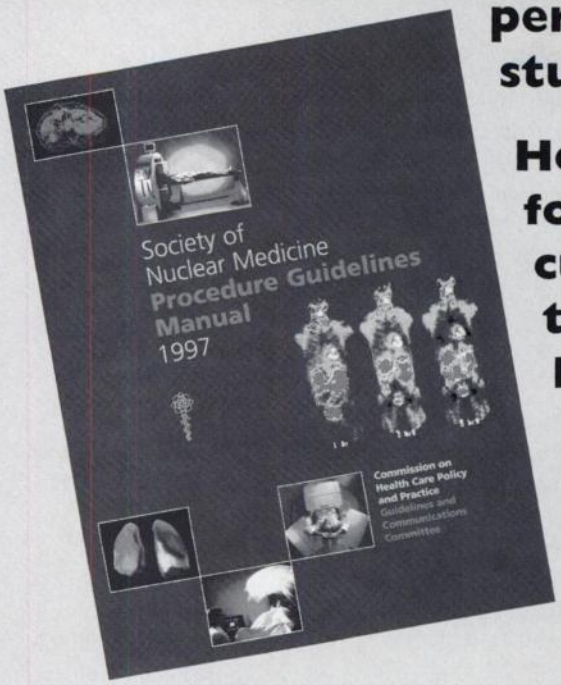
Chair, SNM Committee on Publications
1850 Samuel Morse Dr.
Reston, VA 20190-5316

Do you know the most effective and efficient way to perform a myocardial perfusion study?



How does your procedure for performing renal studies for renovascular hypertension compare with the procedure recommended by leading nuclear medicine experts?

How should you modify your procedures for adult patients when they are performed in pediatric patients?

The answers to these questions and more may be found in the 1997 Society of Nuclear Medicine Procedure Guidelines Manual. This publication will help you achieve high quality nuclear medicine studies to insure that your patients get the treatment they deserve. This informative and useful reference tool is now available for only $20.00. To order your copy, contact Olivia Wong at (703)708-9000 x250 or via e-mail at owong@snm.org

C O N T E N T S I N C L U D E

1997 ★ PR STARS ★ CONTEST

new prizes!

1st Place:

$600 for the Institution and $600 for the Individual. Plus up to $600 in airfare to the 1998 SNM Annual Meeting in Toronto.

2nd Place:

$400 for the Institution and $400 for the Individual.

3rd Place:

$250 for the Institution and $250 for the Individual.

Mail or fax your entry information by December 1, 1997 to:

Society of Nuclear Medicine
1997 PR Stars Contest
1850 Samuel Morse Dr.
Reston, VA 20190-5316

Fax
703-708-9018

Telephone
703-708-9000

One of the goals of the Society of Nuclear Medicine Technologist Section (SNM-TS) has been to take an active role in educating the public and the medical community about nuclear medicine procedures and the benefits of this functional imaging modality.

This is the official entry for the 1997 PR Stars Contest sponsored by the SNM-TS and Technology Imaging Services. Please fill out the entry form and complete the requested information on the reverse side. Based on the information you provide, a panel of judges will evaluate the entries using the point system outlined on the reverse side of this page and select a winner. All entrants must be a Nuclear Medicine Technologist and staff members of a hospital or nuclear medicine facility. Entries must be postmarked no later than December 1, 1997.

Entrant Information:

Your Name: .....

Hospital/Facility: .....

Address: .....

City: .....

State: .....

Zip: .....

Telephone: .....

Fax: .....

Please provide the information requested on the reverse side

1997 ★ PR STARS ★ CONTEST

Please describe and document your promotional activities and results. All original materials will be returned upon completion of the contest. The following point systems will be used for judging.

Please use the check list to assure all questions are answered.

..... **1.** Please compose a detailed description, including the goals and objectives, of your nuclear medicine PR activities. (7 points)

..... **2.** Did the goals and objectives you set reflect those of the PR Stars Contest to:
a. Reinforce nuclear medicine to referring physicians? (10 points)
b. Promote nuclear medicine to healthcare workers? (5 points)
c. Increase community awareness? (5 points)
d. Encourage career paths? (5 points)

..... **3.** How effective were you in reaching the goals of the PR Stars Contest?
a. Increasing physician referrals? (10 points)
b. Increasing awareness among healthcare workers? (5 points)
c. Increasing community awareness? (5 points)
d. Encouraging career paths? (5 points)
e. Showing pride in your profession. (5 points)

..... **4.** What available resources did you use? (budget, manpower, media, etc...) (3 points)

..... **5.** How effectively did you use the available resources? (10 points)

..... **6.** How practical was your program?
a. Can it be easily used by others? (5 points)
b. Was it cost effective? (5 points)

..... **7.** When did your PR activity take place?

..... **8.** Please provide a detailed time-line of the planning and implementation of your program. (10 points)

For Example:

August 1 Strategic planning session with staff technologists.
August 15 Drafted text regarding nuclear medicine for publication in facility newsletter.

..... **9.** Are you a current member of the SNM-TS? (5 points)

Yes ..... No .....

Thank you for your entry!

Good Luck!

Val Cronin, CNMT
Nuclear Medicine Week Chairperson

45th SNM ANNUAL MEETING

See you in

TORONTO

June 7-11, 1998

Society of Nuclear Medicine
Department: Meeting Services
1850 Samuel Morse Drive
Reston, Virginia 20190-5316
703-708-9000, fax 703-709-9274
http://www.snm.org

Position Available

Biomedical Engineer

Medical instrument corporation seeks a Project Engineer with broad skills for design and development of prototype instruments for use in nuclear medicine. Applicant should have a degree in biomedical, mechanical or electrical engineering and be computer literate in Windows 95 and CAD/CAM. Ideal candidate should have either educational background or related work experience in nuclear physics, dosimerty, radiation therapy and diagnosis, and laser technology. Practical experience in clinical hospital setting a plus. Fluency in German and English preferred. Send resume in confidence to: Capintec Inc., Dept. 697, 6 Arrow Road, Ramsey, NJ 07446. Fax: (201) 825-1336.

Faculty Physician

The University of Chicago Department of Radiology is seeking a faculty physician who is board certified in nuclear medicine with experience and commitment to clinical care, medical education and research. Demonstrated ability to perform independent and scholarly research, direct a laboratory and a proven track record of obtaining federal grant support preferred. Interested parties should send a letter and their CV to the search committee c/o: Anne Healy, The University of Chicago, Department of Radiology, 5841 South Maryland Avenue, Chicago, Illinois 60637. Phone: (773) 702-5906. Fax: (773) 702-2523.

Position Wanted

Nuclear medicine physician, taking ABNM Sept. 1997. Strong oncology background, experienced in all aspects of nuclear medicine including diagnosis and therapy, cardiac, neurologic and general. Excellent CV and research interest. Please respond to Society of Nuclear Medicine, Box #801-97, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

Solid journeyman nuclear medicine physician seeking F/T position. Hard working, high ethical standards. ABNM certified and experienced in all areas. Please respond to Society of Nuclear Medicine, Box #802-97, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

CLINICAL SPECIALIST

PerImmune, a biopharmaceutical company specializing in diagnostic imaging and radiotherapeutics has a position available in the Clinical Marketing Department for a Clinical Specialist. This challenging technical marketing position will involve working closely with our clinical research staff and sales marketing distributor to provide diagnostic imaging applications support and training to customers for our oncology imaging product line.

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1330 Piccard Drive
Rockville, MD 20850
Phone: 301-258-5200 • Fax: 301-840-2161

MEDICAL PHYSICIST

Department of Radiation Oncology, University of Nebraska Medical Center. A faculty position in radiation oncology is available for a PhD in physics/radiation dosimetry. Applicant will join an active group investigating the clinical application of radioimmunoconjugates and radiopharmaceuticals for cancer therapy. Duties primarily include research, with some teaching and clinical service. Requirements include at least two years experience in medical physics, quantitative image processing and internal dosimetry calculations for systemically administered radionuclides. The applicant will assist in the design of clinical trials and is expected to develop an independent extramurally funded research program. The University of Nebraska Medical Center (UNMC) has a cancer program of international scope. The UNMC/Eppley Cancer Center is a National Cancer Institute designated laboratory cancer research center whose major goal is to emphasize translational research. Please provide a letter indicating interest, a current curriculum vitae and the names and addresses of at least three references to:

Rowen K. Zetterman, MD, Interim Chair
UNMC Department of Radiation Oncology
600 South 42nd Street
Omaha, NE 68198-1050
Research office phone: (402) 559-9043
Research office fax: (402) 559-8112

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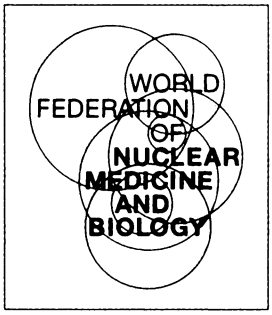

Joint WFNM&B and EANM Congress

7th World Congress of Nuclear Medicine and Biology

Berlin
August 30 – September 4, 1998

(co-sponsored by the World Health Organization)

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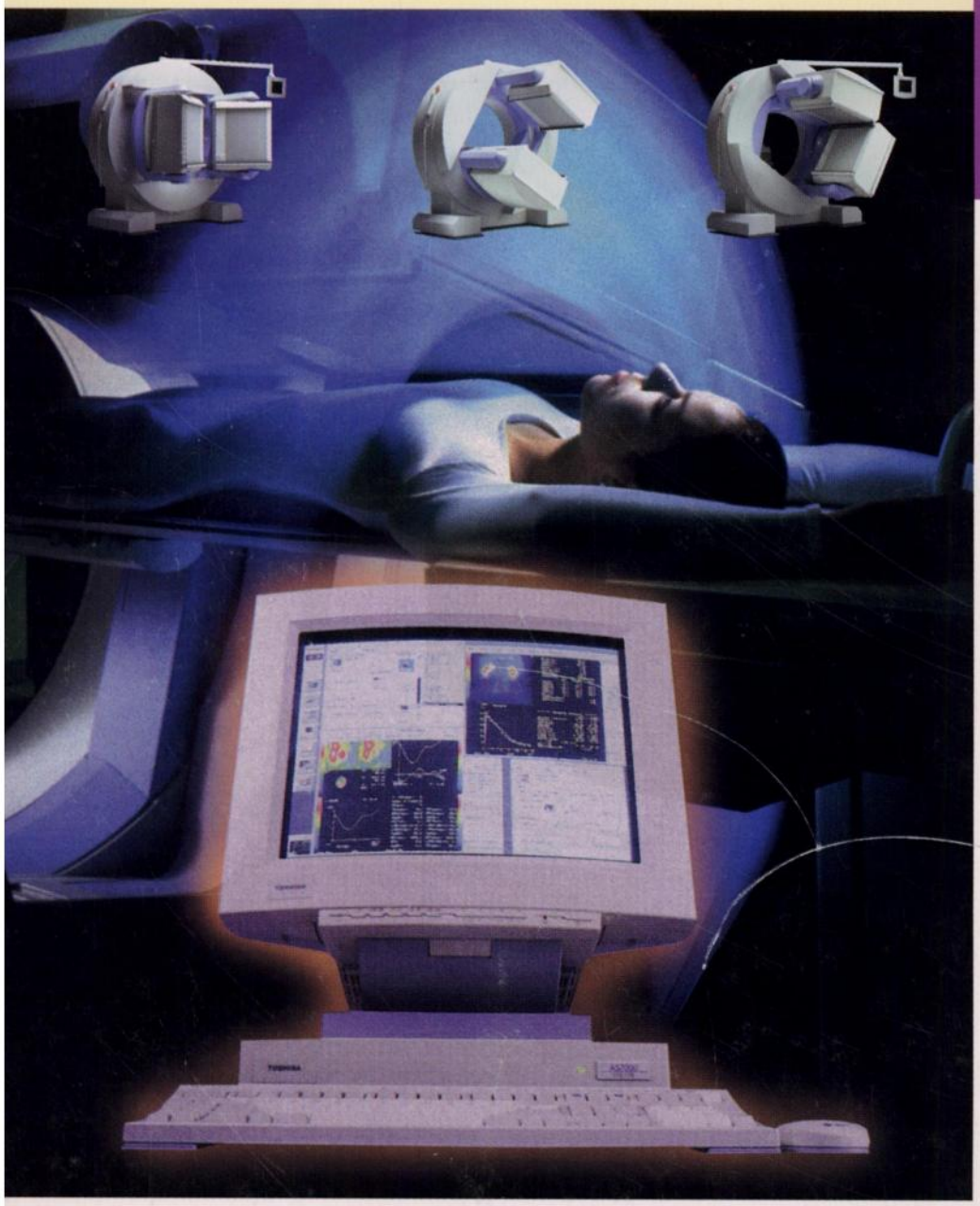

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