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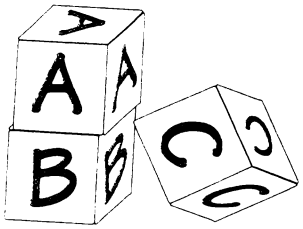

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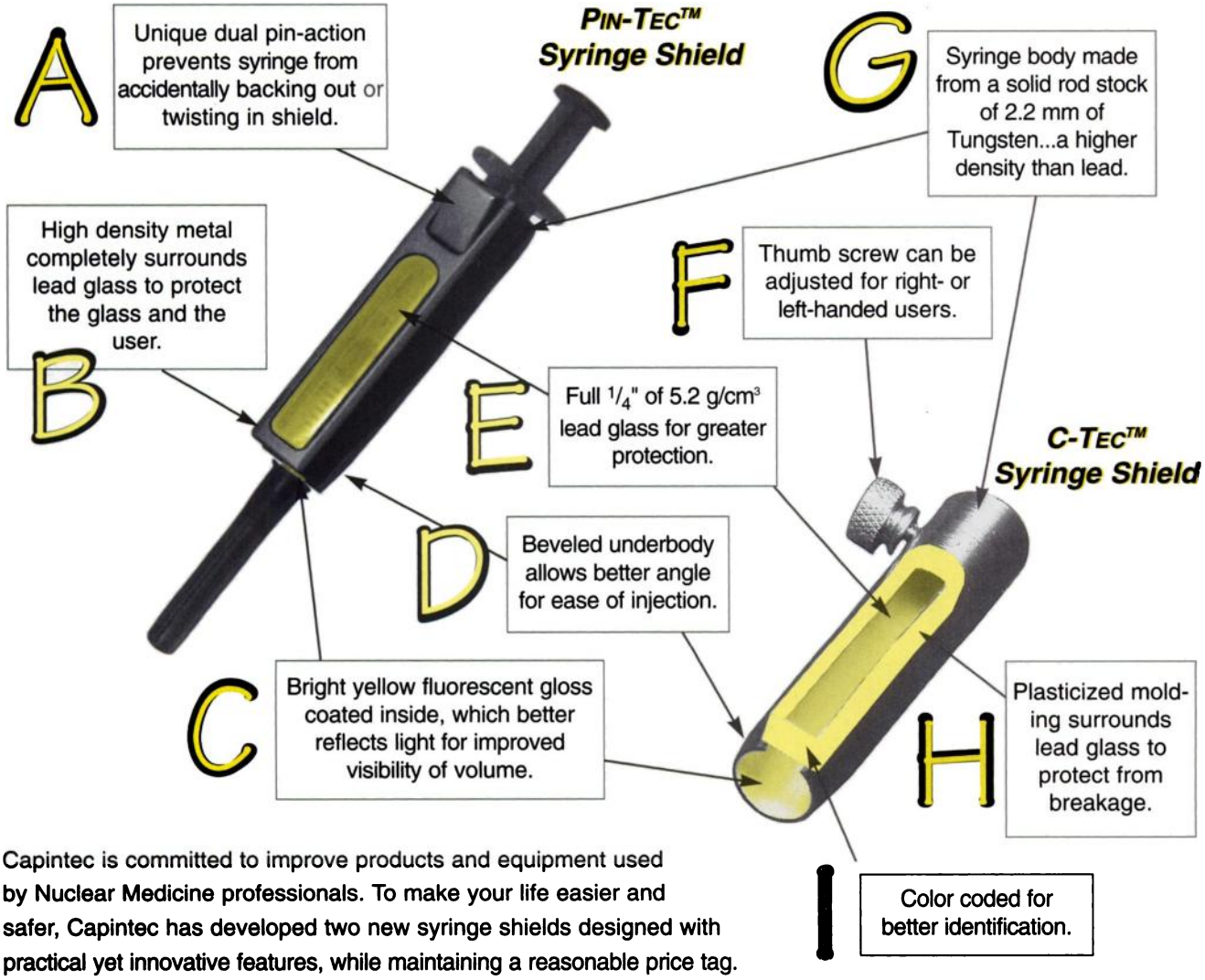

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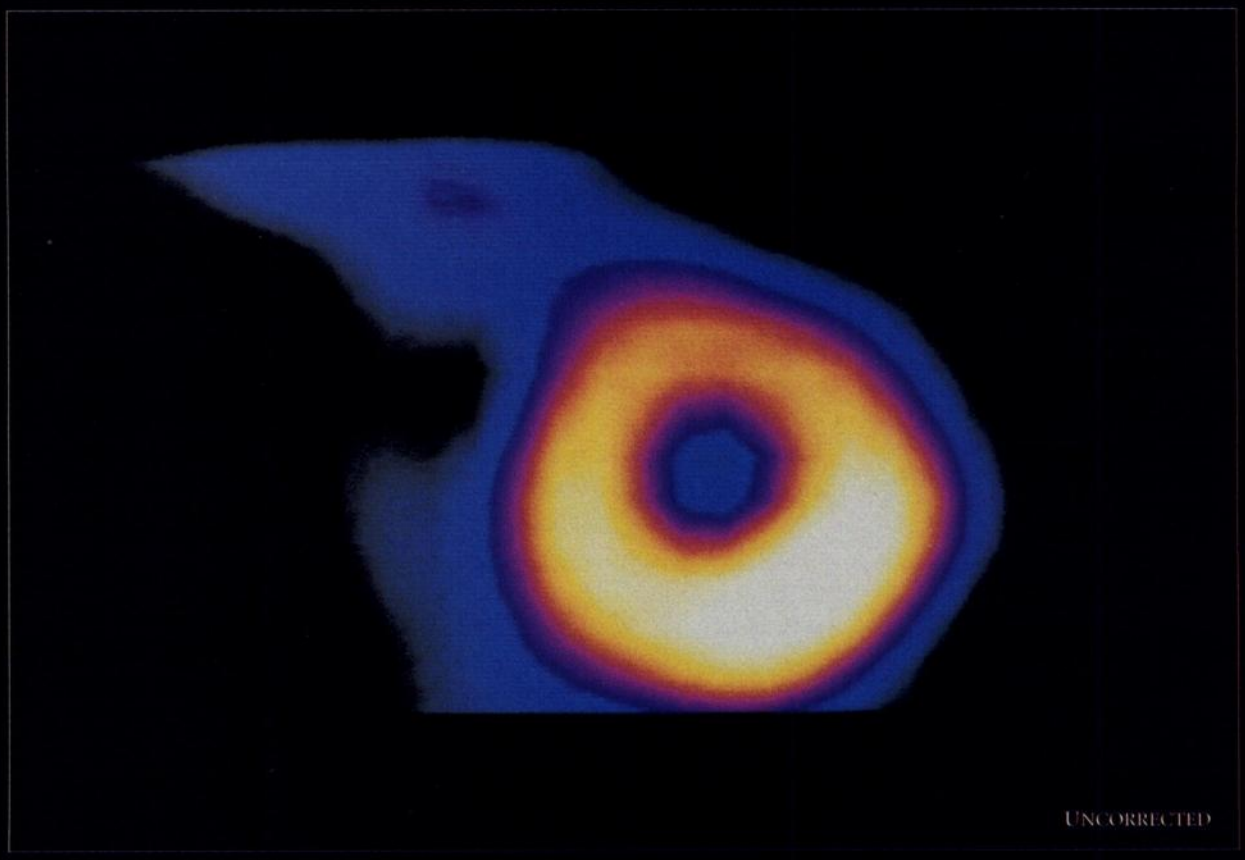

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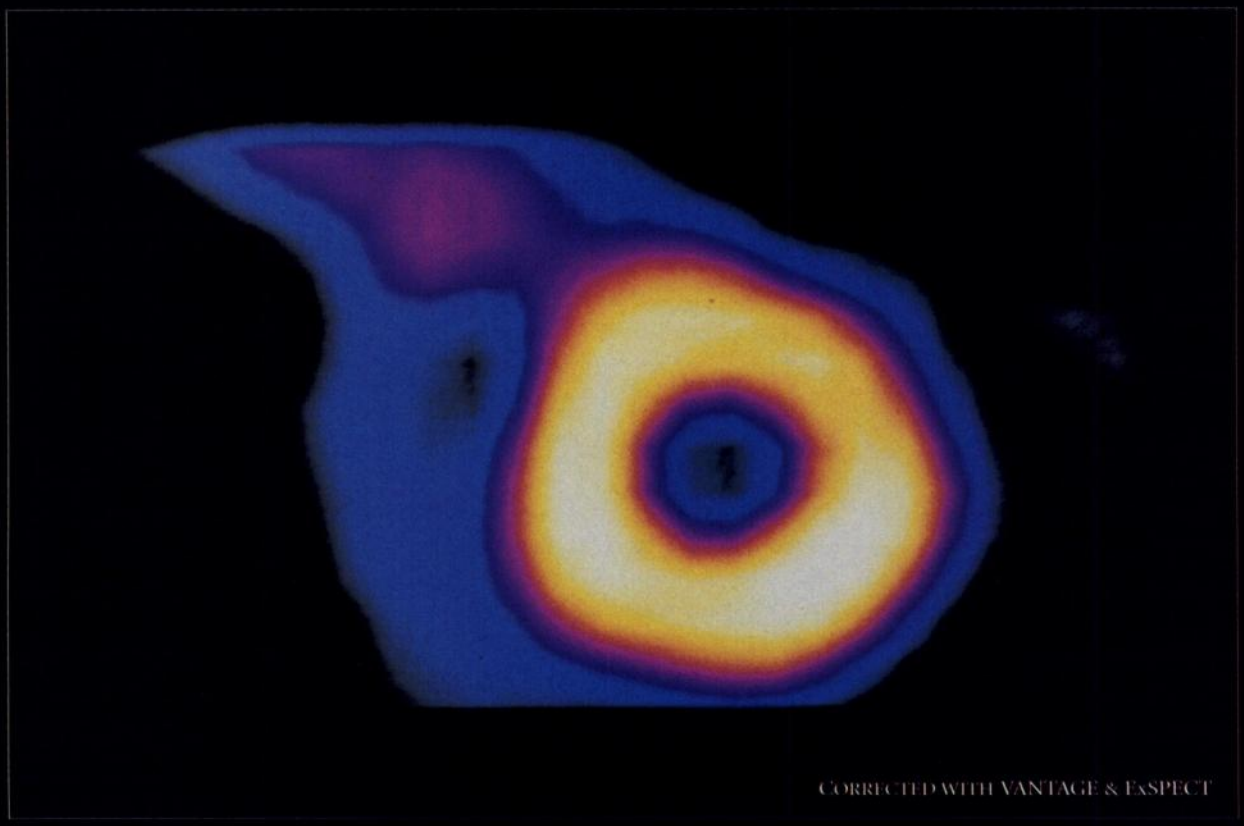

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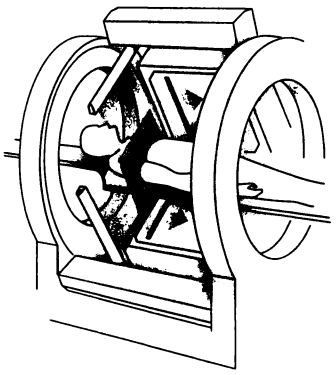

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Please review the following abstracts that are published in this year's *Journal of Nuclear Medicine* SNM abstract journal.

CORRECTION OF PHOTON ATTENUATION IN SPECT MYOCARDIAL PERFUSION IMAGING: PRELIMINARY RESULTS OF A MULTICENTER TRIAL.

R.C. Hendel, H. Kiat, W.P. Follansbee, G.V. Heller, S.J. Cullom, D.S. Berman

COMPARISON OF SUPINE, PRONE AND ATTENUATION CORRECTED STRESS TC-99M SESTAMIBI MYOCARDIAL PERFUSION SPECT.

H.Kiat, S. Reuter, K. Van Train, M. Patterson, J. Areeda, X. Kang, G. Germano, R.C. Hendel, MD*, J.D. Friedman, D.S. Berman

COMPENSATION OF ATTENUATION MAP ERRORS FROM TC-99M-SESTAMIBI DOWNSCATTER WITH SIMULTANEOUS GD-153 TRANSMISSION SCANNING.

S.J. Cullom, L. Liu and M.L. White

DIAGNOSTIC ACCURACY AND IMAGE QUALITY OF A SCATTER, ATTENUATION AND RESOLUTION COMPENSATION METHOD FOR TC-99M-SESTAMIBI CARDIAC SPECT: PRELIMINARY RESULTS.

S.J. Cullom, R.C. Hendel*, L. Lin, E.V. Garcia, M.L. White, H. Kiat** and D.S. Berman**

A MODIFIED WIENER FILTER METHOD FOR NONSTATIONARY RESOLUTION RECOVERY WITH SCATTER AND ITERATIVE ATTENUATION CORRECTION FOR CARDIAC SPECT.

L. Liu, S.J. Cullom, and M.L. White

EVALUATION OF A SCANNING LINE SOURCE METHOD FOR ATTENUATION CORRECTION USING AN ANTHROPOMORPHIC PHANTOM.

M.W. Groch, S.M. Spies, H. Hines*, J. Liebeg*, R.C. Hendel

PHOTON ATTENUATION CORRECTION USING A GADOLINIUM-153 LINE SOURCE REDUCES REGIONAL MYOCARDIAL COUNT HETEROGENEITY IN NORMAL PATIENTS UNDERGOING TC-99M SESTAMIBI SINGLE PHOTON TOMOGRAPHY: IMPLICATIONS FOR QUANTITATIVE ANALYSIS.

Z-X He, S. Gangalopady, G. Reyes, M.S. Verani and J.J. Mahmarian

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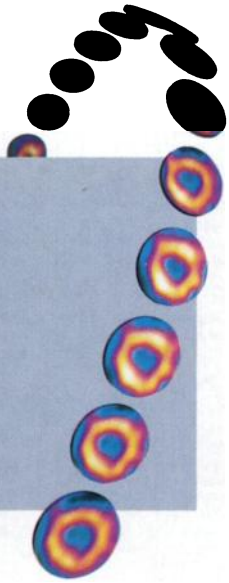

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Kit for the preparation of Technetium Tc99m Sestamibi

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DU PONT PHARMA
Radiopharmaceuticals

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

Brief Summary

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

F O R D I A G N O S T I C U S E

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 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, 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, $[Cu(MIBI)_4]BF_4$, 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 (≥ 20μg/ml), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $[Cu(MIBI)_4]BF_4$ 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 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 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

	Estimated Radiation Absorbed Dose			
	REST			
	2.0 hour void		4.8 hour void	
Organ	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
	STRESS			
	2.0 hour void		4.8 hour void	
Organ	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.8
Gallbladder Wall	2.8	28.9	2.8	27.8
Small Intestine	2.4	24.4	2.4	24.4
Upper Large Intestine Wall	4.5	44.4	4.5	44.4
Lower Large Intestine Wall	3.3	32.2	3.3	32.2
Stomach Wall	0.5	5.3	0.5	5.2
Heart Wall	0.5	5.6	0.5	5.3
Kidneys	1.7	16.7	1.7	16.7
Liver	0.4	4.2	0.4	4.1
Lungs	0.3	2.6	0.2	2.4
Bone Surfaces	0.6	6.2	0.6	6.0
Thyroid	0.3	2.7	0.2	2.4
Ovaries	1.2	12.2	1.3	13.3
Testes	0.3	3.1	0.3	3.4
Red Marrow	0.5	4.6	0.5	4.4
Urinary Bladder Wall	1.5	15.5	3.0	30.0
Total Body	0.4	4.2	0.4	4.2

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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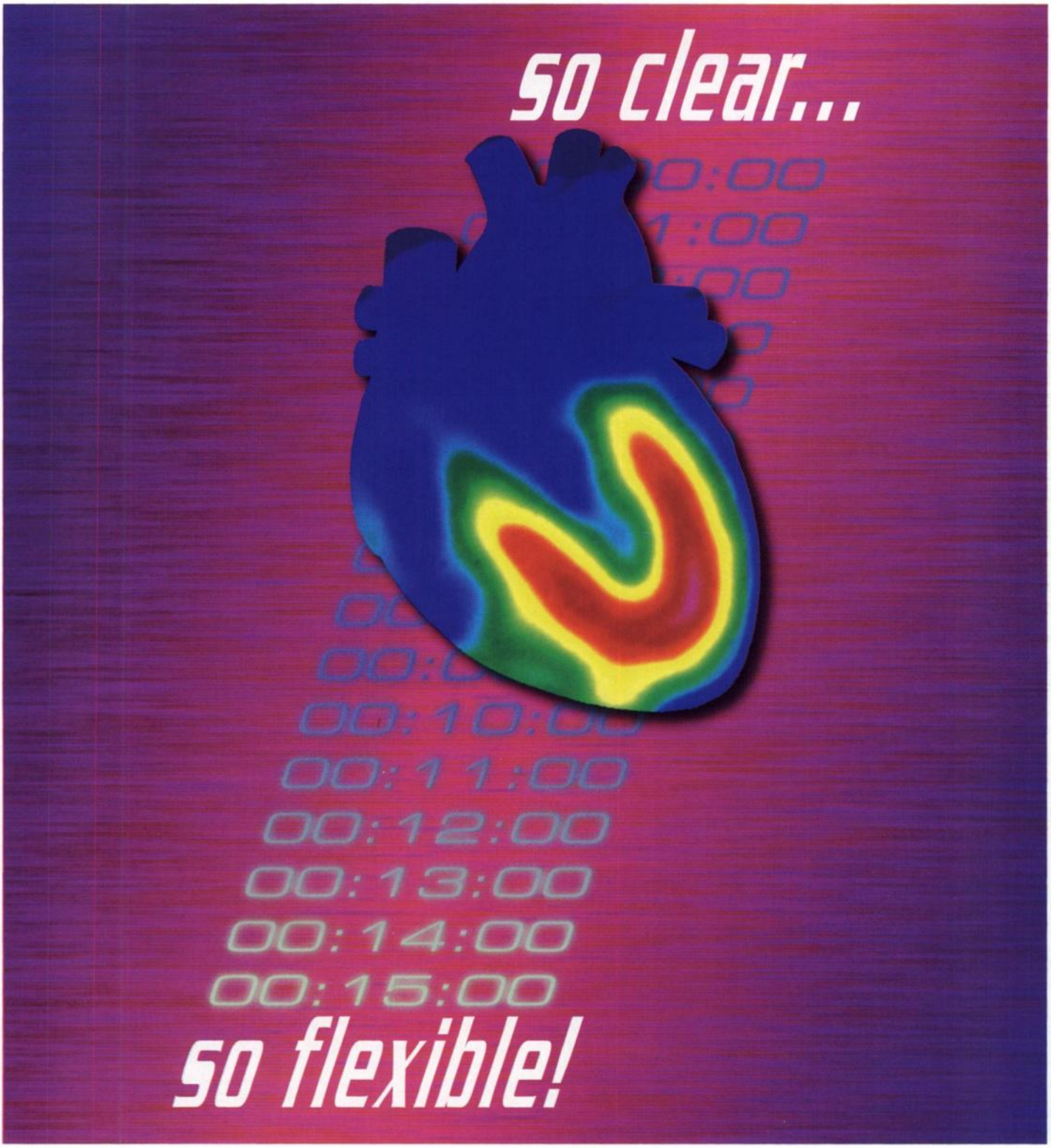
MYOVIEW™

Technetium Tc99m Tetrofosmin For Injection



Amersham HEALTHCARE

See brief summary of prescribing information on the following page.

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.

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

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with colorectal or recurrent ovarian adenocarcinoma

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ONCOSCINT® CR/OV

Satumomab Pendetide (1 mg/2 mL)

A tumor-targeted
road map
to monitor and stage cancer

- For presurgical staging to plan or potentially alter the operative approach[1]
- Assists in planning individual treatment before surgery[1]
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ONCOSCINT® CR/OV
Satumomab Pendetide (1 mg/2 mL)

*Human antimurine antibody.

Please see brief summary of prescribing information on adjacent page.

OncoScint® CR/OV Kit (satumomab pendetide)

Kit for the Preparation of Indium In 111 satumomab pendetide
For Intravenous Use Only

Brief Summary of Prescribing Information

INDICATIONS AND USAGE
OncoScint® CR/OV-In (indium In 111 satumomab pendetide) is a diagnostic imaging agent that is indicated for determining the extent and location of extrahepatic malignant disease in patients with known colorectal or ovarian cancer. Clinical studies suggest that this imaging agent should be used after completion of standard diagnostic tests when additional information regarding disease extent could aid in patient management. The diagnostic images acquired with OncoScint® CR/OV-In should be interpreted in conjunction with a review of information obtained from other appropriate tests.
OncoScint® CR/OV-In is also indicated for re-administration to HAMA-negative patients who are at risk of recurrence. Ordering physicians should be aware that HAMA-positive patients have alterations in the biodistribution of the radioimmunoconjugate and in the quality of imaging. Therefore it is vital that before any repeat use of OncoScint® CR/OV-In HAMA levels should be determined in pre-infusion sera. The results should be evaluated with respect to the patient's clinical situation and the guidelines below should be followed.
Repeat OncoScint® CR/OV-In should not be given to persons whose HAMA level is > 400 ng/mL because of the possibility of infusional reactions, and uniformly altered biodistribution and poor quality images. In general, if HAMA values are < 50 ng/mL most subjects will image normally. Altered biodistribution may occur in 3-4% (3/80 samples) of cases for unknown reasons unrelated to HAMA level. If HAMA values are between 50 and 400 ng/mL there is a higher incidence of subjects who will show altered biodistribution (7/13 samples) and uninformative imaging; in this range the frequency of HAMA interference with imaging has yet to be determined.
OncoScint® CR/OV-In is not indicated as a screening test for ovarian or colorectal cancer.
Administration of OncoScint® CR/OV-In may result in falsely elevated values from in vitro immunoassays, including tests for carcinoembryonic antigen (CEA) and CA 125. Because this interference may persist for months, the clinical laboratory should investigate for assay interference in patients who develop elevated CEA or CA 125 subsequent to imaging with OncoScint® CR/OV-In (see *Drug/Laboratory Test Interactions*).

In HAMA*-negative patients with colorectal or recurrent ovarian adenocarcinoma

ONCOSCINT® CR/OV
Satumomab Pendetide (1mg/2mL)

A tumor-targeted road map to monitor and stage cancer

Please refer to complete prescribing information before using **OncoScint CR/OV**.

CONTRAINDICATIONS
OncoScint® CR/OV-In (indium In 111 satumomab pendetide) should not be used in patients who are hypersensitive to this or any other product of murine origin or to indium In 111 chloride.

WARNINGS
Allergic reactions, including anaphylaxis, can occur in patients who receive murine antibodies. Although serious reactions of this type have not been observed in clinical trials after OncoScint® CR/OV-In (indium In 111 satumomab pendetide) administration, medications for the treatment of hypersensitivity reactions should be available during administration of this agent.

PRECAUTIONS
General The components of the kit are sterile and pyrogen free and contain no preservative. OncoScint® CR/OV-In (indium In 111 satumomab pendetide) should be used within 8 hours after radiolabeling. It is essential to follow the directions for preparation carefully and to adhere to strict aseptic procedures during preparation of the radiolabeled product.
Each OncoScint® CR/OV kit is a unit of use package. The contents of the kit are to be used only to prepare OncoScint® CR/OV-In; unlabeled OncoScint® CR/OV should NOT be administered directly to the patient. After radiolabeling with indium-111, the entire OncoScint® CR/OV-In dose must be administered to the patient for whom it was prescribed. **Reducing the dose of either component may adversely impact imaging results, and, therefore, is not recommended.**
The contents of the kit are not radioactive. However, after the indium In 111 chloride is added, appropriate shielding of OncoScint® CR/OV-In must be maintained. Care should be taken to minimize radiation exposure to patients and medical personnel, consistent with proper hospital and patient management procedures.
In addition, radiopharmaceuticals should be used only by physicians and other professionals who are qualified by training and experience in the safe use and handling of radionuclides.

Information for Patients Murine monoclonal antibodies are foreign proteins, and their administration can induce human anti-murine antibodies (HAMA). While limited data exist concerning the clinical significance of HAMA, the presence of HAMA may interfere with murine-antibody based immunoassays, could compromise the efficacy of diagnostic or therapeutic murine antibody-based agents, and may increase the risk of adverse reactions. For these reasons, patients should be informed that the use of this product could affect the future use of other murine-based products, including OncoScint® CR/OV-In, and should be advised to discuss prior use of murine-antibody based products with their physicians.
OncoScint® CR/OV-In has been shown to induce HAMA to murine IgG after single administration in about 55% of patients in tumor imaging trials. HAMA levels became negative in one-third of such patients by 6 months after infusion.
While limited data exist concerning the clinical significance of HAMA, it is known that patients who develop persistently elevated serum HAMA levels have altered clearance and tissue biodistribution of MAbs. The efficacy of diagnostic or therapeutic murine antibody-based agents may be compromised in these patients.
When considering the administration of OncoScint® CR/OV-In to patients who have previously received murine antibody-based products, physicians should be aware of the potential for HAMA to alter clearance and biodistribution. The quality or sensitivity of the imaging study may be compromised. Therefore, prior to administration of murine antibodies, including OncoScint® CR/OV-In, the physician should review the patient history to determine whether the patient has previously received such products.
Prior to administration of OncoScint® CR/OV-In, patients who have previously received this or other murine antibody-based products should be tested for HAMA using approved methodology. Specialty Laboratories, Inc. (Santa Monica, California) has CYTOGEN approved methodology that measures HAMA by its ability to bridge between solid-phase murine antibody and soluble, radiolabeled murine antibody.
Clinical trials which utilize this methodology demonstrated that if serum HAMA levels are less than 50 ng/mL, there is a high probability of high image quality associated with the normal biodistribution of OncoScint® CR/OV-In. If HAMA levels are between 50 and 400 ng/mL the biodistribution of the agent is likely to be abnormal. If the serum HAMA level is greater than 400 ng/mL, repeat imaging studies should not be performed.
Instructions regarding the preparation and shipment of serum samples for HAMA testing can be obtained by contacting Specialty Laboratories 1-800-421-7110 (Fax 310-828-6634).

Drug/Laboratory Test Interactions The presence of HAMA in serum may interfere with two-site murine antibody-based immunoassays, including assays for carcinoembryonic antigen (CEA) and CA 125. When present, this interference generally results in falsely high values. If HAMA is known or suspected to be present, the clinical laboratory should be notified and appropriate measures taken to avoid this interference. These methods include the use of non-murine immunoassays, or HAMA removal by adsorption, blocking, or heat inactivation.
Carcinogenesis, Mutagenesis, Impairment of Fertility Long-term animal studies have not been performed to evaluate the carcinogenic or mutagenic potential of OncoScint® CR/OV-In or to evaluate its effect on fertility in males or females.
Pregnancy Category C Animal reproduction studies have not been conducted with OncoScint® CR/OV-In. It is also not known whether OncoScint® CR/OV-In can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. OncoScint® CR/OV-In should not be administered to a pregnant woman unless, in the opinion of the physician, the information to be gained outweighs the potential risks. MAb B72.3 has been shown to react with fetal gastrointestinal tissues.
In general, examinations using radiopharmaceuticals in women of childbearing potential should be performed during the first few days (approximately 10) following the onset of menses.

Nursing Mothers and/or Lactating Women It is not known whether OncoScint® CR/OV-In is excreted in human milk and, if so, for how long. Because many drugs are excreted in human milk, caution should be exercised when OncoScint® CR/OV-In is administered to a nursing woman. OncoScint® CR/OV-In has not been administered to lactating females and therefore should not be administered to nursing mothers unless, in the opinion of the physician, the information to be gained outweighs the potential risk. In such cases, formula feedings should be substituted for breast feedings.
Pediatric Use The safety and effectiveness of OncoScint® CR/OV-In in children have not been established.

ADVERSE REACTIONS
After administration of 1188 i.v. doses of OncoScint® CR/OV-In (indium In 111 satumomab pendetide) to 1041 patients in clinical trials, adverse reactions were observed in approximately 4% of patients. No deaths attributable to OncoScint® CR/OV-In administration were reported. The most common adverse reaction was fever, which occurred in approximately 1% of patients. Other adverse reactions, each of which occurred in less than 1% of patients, are listed in order of decreasing frequency: hypotension, hypertension, nausea, chills, rash, injection site reactions, pruritus, allergic reactions, sweating, abdominal pain, asthenia, chest pain, headache, hypothermia, pain, bradycardia, vasodilatation, diarrhea, arthralgia, confusion, dizziness, nervousness, crying, and angioedema. Although causality was not determined, an isolated occurrence of reversible thrombocytopenia was observed in a patient who received OncoScint® CR/OV-In in clinical trials.
The overall incidence of adverse reactions reported for repeat administration of OncoScint® CR/OV-In (4%) is similar to that observed after administration of single, initial doses. Of the adverse reactions listed above, two fevers, one report of abdominal pain, and two readily reversible hypersensitivity reactions characterized primarily by flank pain have been reported after repeat doses of OncoScint® CR/OV-In. The latter two patients had positive preinjection HAMA titers and a history of allergies.

OVERDOSAGE
The maximum amount of OncoScint® CR/OV-In (indium In 111 satumomab pendetide) that can be safely administered has not been determined. In clinical trials, single doses of 20 mg of OncoScint® CR/OV-In were administered to 64 patients with various types of epithelial carcinomas; the type and frequency of adverse reactions at this dose were similar to those observed with lower doses.

DOSAGE AND ADMINISTRATION
The dose of OncoScint® CR/OV (satumomab pendetide) is 1 mg radiolabeled with 5 mCi of indium In 111 chloride. Each dose is administered intravenously over 5 minutes and should not be mixed with any other medication during its administration. The patient dose of the radiolabel should be measured in a dose calibrator prior to administration.
Each OncoScint® CR/OV kit is a unit dose package. After radiolabeling with indium-111, the entire OncoScint® CR/OV-In dose should be administered to the patients. **Reducing the dose of either component may adversely impact imaging results, and is, therefore, not recommended.**

HOW SUPPLIED
The OncoScint® CR/OV kit (NDC No. 57902-640-01) for the preparation of indium-111 labeled OncoScint® CR/OV includes one vial containing 1 mg of satumomab pendetide per 2 mL of sodium phosphate buffered saline and one 2 mL vial of sodium acetate buffer solution, 0.5 *M*. These solutions are sterile and pyrogen free and contain no preservative. Each kit also includes one sterile 0.22 µm Millex® GV filter, prescribing information, and two identification labels.

Manufactured by:
CYTOGEN Corporation
Princeton, NJ

Revised 8/95

* Human antimurine antibody

References: **1.** Doerr RJ, Abdel-Nabi H, Krag D, et al. Radiolabeled antibody imaging in the management of colorectal cancer: results of a multicenter clinical study. *Ann Surg.* 1991;214(2):118-124. **2.** Data on file. Cytogen Corporation, Princeton, NJ.

01024/2-96

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Manufactured and distributed by:
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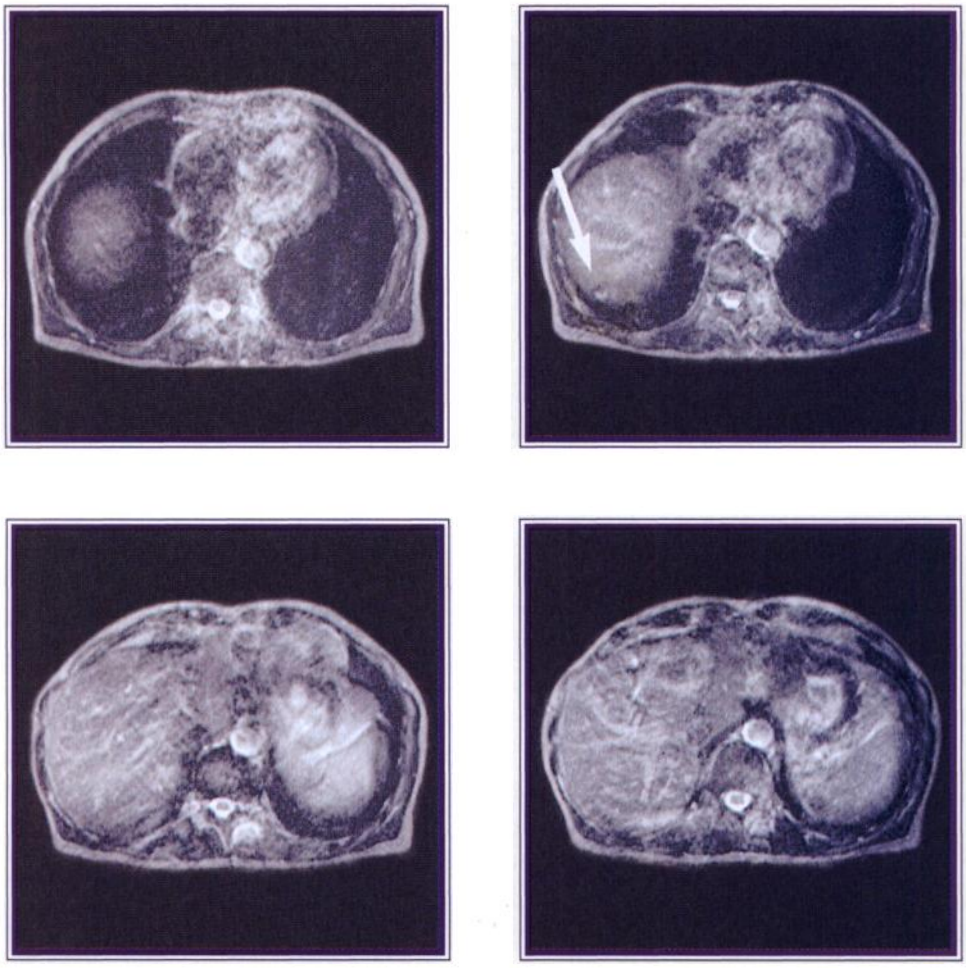
Recurrent Carcinoid Tumor

Abdominal MRI indicated evidence of recurrent disease...



Abdominal MRI indicating evidence of hepatic tumor.

OctreoScan imaging identified additional metastases for surgical intervention

Patient History

This middle-aged male underwent resection of a pancreatic carcinoid tumor four years ago. Subsequent 3 and 4 year CT scans presented evidence of recurrent disease. The patient was referred for OctreoScan imaging.

OctreoScan Scintigraphy

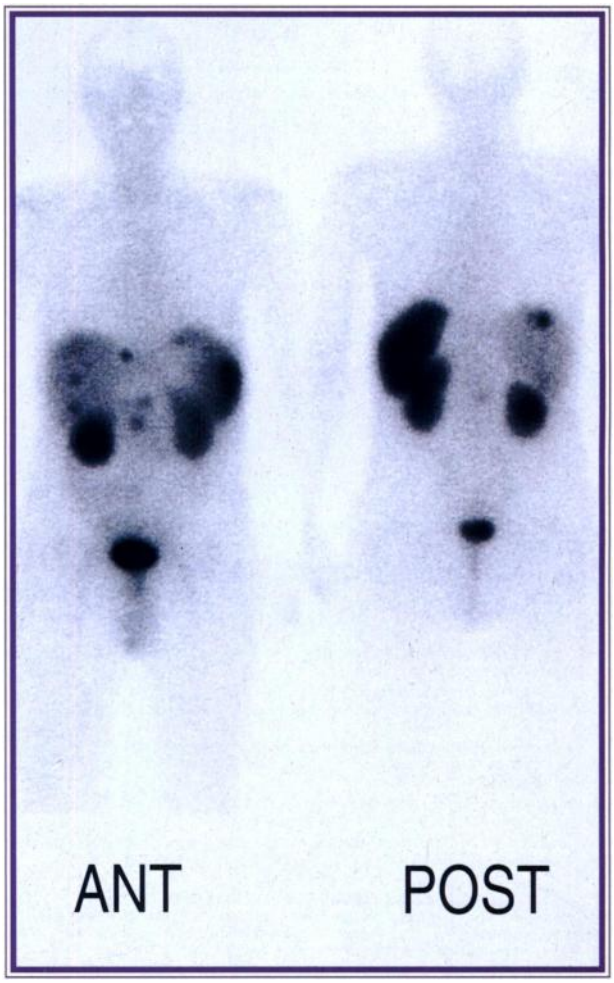
Five hepatic tumors and two periaortic nodal lesions were clearly visible on the whole-body planar images. OctreoScan imaging enabled differentiation between a non-receptor-expressing cavernous hemangioma and receptor-positive carcinoid metastases.

Clinical Course

Correlative MRI indicated disease, but some lesions would likely have been missed without the benefit of OctreoScan scintigraphy. The patient underwent surgery to freeze all five hepatic lesions identified by OctreoScan. Follow-up MRI and OctreoScan studies were planned to assess post-operative status.

Decisive Clinical Information

In patients who have a known or suspected neuroendocrine tumor, OctreoScan imaging often can be the difference between cautious uncertainty and decisive clinical intervention. Contact your nuclear medicine specialist for more information.



OctreoScan whole-body images showing five hepatic lesions and two periaortic lesions.

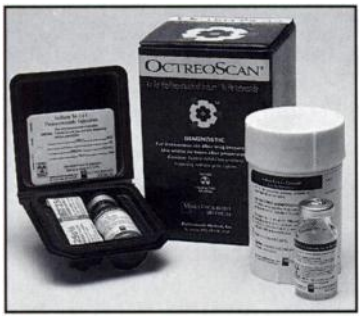
OCTREOSCAN®
Kit for the Preparation of Indium In-111 Pentetreotide

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 radiopharmaceutical. 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 doses[1] 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 Pentetreotide[3] 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-hemicystyl-L-phenylalanyl-D-tryptophyl-L-lysyl-L-threonyl-L-hemicystyl-L-threoninol 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 MEDICAL

Mallinckrodt Medical, Inc.,
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St. Louis, MO 63134

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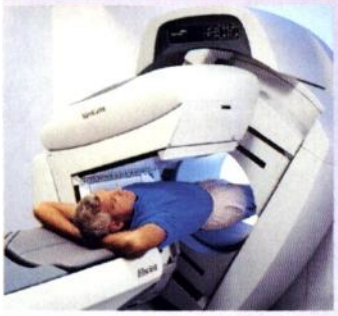
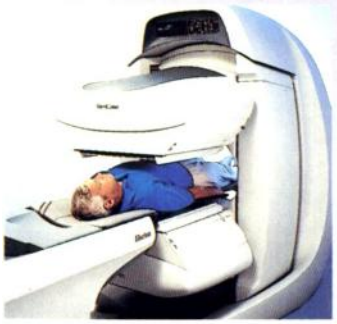
VariCam Get an angle on the future...





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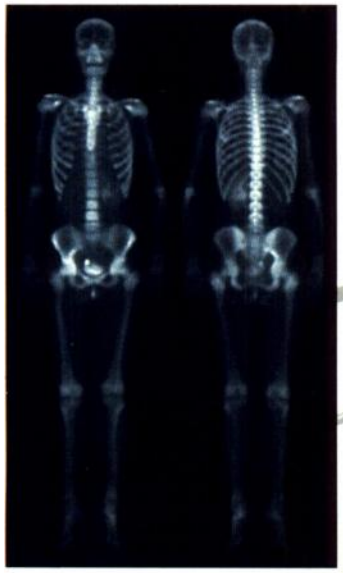

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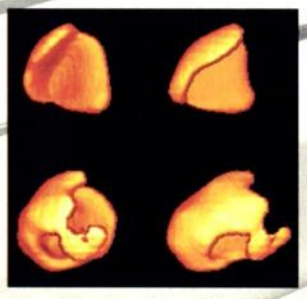

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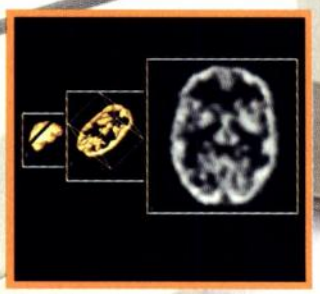
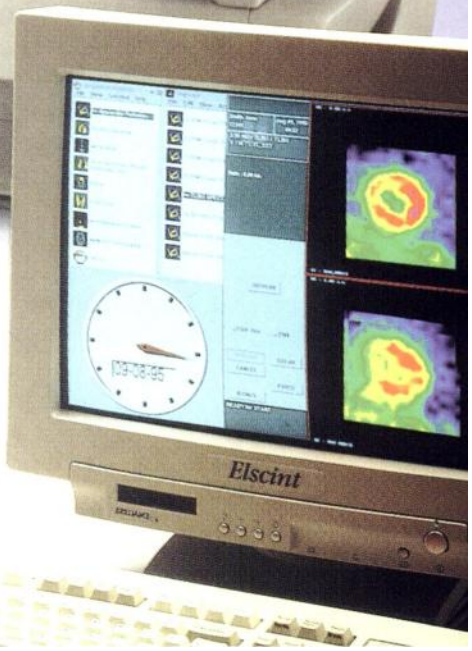


Double double-efficiency
Volumetric Coincidence Detection

**Work-in-progress*



Elscint

SNM Annual Meeting Booths 401, 601 and 701
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Imaging comparable to maximal exercise

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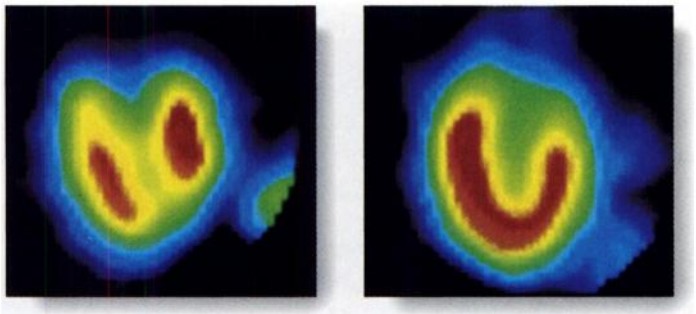
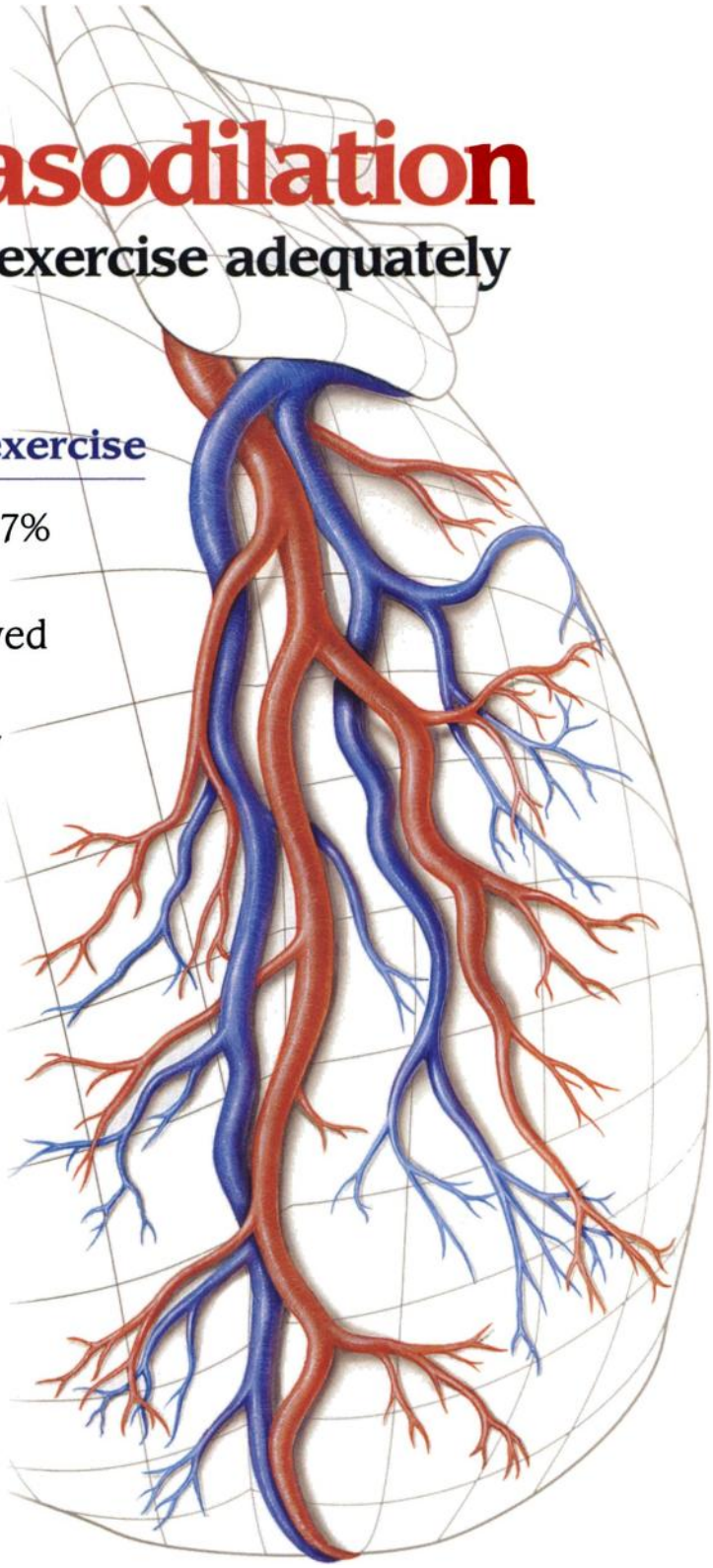


Stress *Redistribution*

Rapid onset, short duration

- <10-second half-life minimizes post-infusion monitoring time
- Side effects usually resolve quickly



ADENOSCAN®

adenosine

Please see brief summary of prescribing information on adjacent page for warnings, precautions and contraindications.

Fujisawa

1. Cerquiera MD, Verani MS, Schwaiger M, et al. Safety profile of adenosine stress perfusion imaging: results from Adenoscan multicenter trial registry. *J Am Coll Cardiol.* 1994;23:384-389.

BRIEF SUMMARY

ADENOSCAN®
adenosine

For Intravenous Infusion Only

DESCRIPTION

Adenosine is an endogenous nucleoside occurring in all cells of the body. It is chemically 6-amino-9-beta-D-ribofuranosyl-9-H-purine.

Adenosine is a white crystalline powder. It is soluble in water and practically insoluble in alcohol. Solubility increases by warming and lowering the pH of the solution.

Each Adenoscan vial contains a sterile, non-pyrogenic solution of adenosine 3 mg/mL and sodium chloride 9 mg/mL in Water for Injection, q.s. The pH of the solution is between 4.5 and 7.5.

INDICATIONS AND USAGE:

Intravenous Adenoscan is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. (See **WARNINGS**).

CONTRAINDICATIONS:

Intravenous Adenoscan (adenosine) should not be administered to individuals with:

1. Second- or third-degree AV block (except in patients with a functioning artificial pacemaker).
2. Sinus node disease, such as sick sinus syndrome or symptomatic bradycardia (except in patients with a functioning artificial pacemaker).
3. Known or suspected bronchoconstrictive or bronchospastic lung disease (e.g., asthma).
4. Known hypersensitivity to adenosine.

WARNINGS:

Fatal Cardiac Arrest, Life Threatening Ventricular Arrhythmias, and Myocardial Infarction.

Fatal cardiac arrest, sustained ventricular tachycardia (requiring resuscitation), and nonfatal myocardial infarction have been reported coincident with Adenoscan infusion. Patients with unstable angina may be at greater risk.

Sinoatrial and Atrioventricular Nodal Block

Adenoscan (adenosine) exerts a direct depressant effect on the SA and AV nodes and has the potential to cause first-, second- or third-degree AV block, or sinus bradycardia. Approximately 6.3% of patients develop AV block with Adenoscan, including first-degree (2.9%), second-degree (2.6%) and third-degree (0.8%) heart block. All episodes of AV block have been asymptomatic, transient, and did not require intervention. Adenoscan can cause sinus bradycardia. Adenoscan should be used with caution in patients with pre-existing first-degree AV block or bundle branch block and should be avoided in patients with high-grade AV block or sinus node dysfunction (except in patients with a functioning artificial pacemaker). Adenoscan should be discontinued in any patient who develops persistent or symptomatic high-grade AV block. Sinus pause has been rarely observed with adenosine infusions.

Hypotension

Adenoscan (adenosine) is a potent peripheral vasodilator and can cause significant hypotension. Patients with an intact baroreceptor reflux mechanism are able to maintain blood pressure and tissue perfusion in response to Adenoscan by increasing heart rate and cardiac output. However, Adenoscan should be used with caution in patients with autonomic dysfunction, stenotic valvular heart disease, pericarditis or pericardial effusions, stenotic carotid artery disease with cerebrovascular insufficiency, or uncorrected hypovolemia, due to the risk of hypotensive complications in these patients. Adenoscan should be discontinued in any patient who develops persistent or symptomatic hypotension.

Hypertension

Increases in systolic and diastolic pressure have been observed (as great as 140 mm Hg systolic in one case) concomitant with Adenoscan infusion; most increases resolved spontaneously within several minutes, but in some cases, hypertension lasted for several hours.

Bronchoconstriction

Adenoscan (adenosine) is a respiratory stimulant (probably through activation of carotid body chemoreceptors) and intravenous administration in man has been shown to increase minute ventilation (Ve) and reduce arterial PCO_2 causing respiratory alkalosis. Approximately 29% of patients experience breathlessness (dyspnea) or an urge to breathe deeply with Adenoscan. These respiratory complaints are transient and only rarely require intervention.

Adenosine administered by inhalation has been reported to cause bronchoconstriction in asthmatic patients, presumably due to mast cell degranulation and histamine release. These effects have not been observed in normal subjects. Adenoscan has been administered to a limited number of patients with asthma and mild to moderate exacerbation of their symptoms has been reported. Respiratory compromise has occurred during adenosine infusion in patients with obstructive pulmonary disease. Adenoscan should be used with caution in patients with obstructive lung disease not associated with bronchoconstriction (e.g., emphysema, bronchitis, etc.) and should be avoided in patients with bronchoconstriction or bronchospasm (e.g., asthma). Adenoscan should be discontinued in any patient who develops severe respiratory difficulties.

PRECAUTIONS:

Drug Interactions

Intravenous Adenoscan (adenosine) has been given with other cardioactive drugs (such as beta adrenergic blocking agents, cardiac glycosides, and calcium channel blockers) without apparent adverse interactions, but its effectiveness with these agents has not been systematically evaluated. Because of the potential for additive or synergistic depressant effects on the SA and AV nodes, however, Adenoscan should be used with caution in the presence of these agents. The vasoactive effects of Adenoscan are inhibited by adenosine receptor antagonists, such as alkylxanthines (e.g., caffeine and theophylline). The safety and efficacy of Adenoscan in the presence of these agents has not been systematically evaluated. The vasoactive effects of Adenoscan are potentiated by nucleoside transport inhibitors, such as dipyridamole. The safety and efficacy of Adenoscan in the presence of dipyridamole has not been systematically evaluated. Whenever possible, drugs that might inhibit or augment the effects of adenosine should be withheld for at least five half-lives prior to the use of Adenoscan.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies in animals have not been performed to evaluate the carcinogenic potential of Adenoscan (adenosine). Adenosine was negative for genotoxic potential in the Salmonella (Ames Test) and Mammalian Microsome Assay.

Adenosine, however, like other nucleosides at millimolar concentrations present for several doubling times of cells in culture, is known to produce a variety of chromosomal alterations. In rats and mice, adenosine administered intraperitoneally once a day for five days at 50, 100, and 150 mg/kg [10-30 (rats) and 5-15 (mice) times human dosage on a mg/M^2 basis] caused decreased spermatogenesis and increased numbers of abnormal sperm, a reflection of the ability of adenosine to produce chromosomal damage.

Pregnancy Category C

Animal reproduction studies have not been conducted with adenosine; nor have studies been performed in pregnant women. Because it is not known whether Adenoscan can cause fetal harm when administered to pregnant women, Adenoscan should be used during pregnancy only if clearly needed.

Pediatric Use

The safety and effectiveness of Adenoscan in patients less than 18 years of age have not been established.

ADVERSE REACTIONS:

The following reactions with an incidence of at least 1% were reported with intravenous Adenoscan among 1421 patients enrolled in controlled and uncontrolled U.S. clinical trials. Despite the short half-life of adenosine, 10.6% of the side effects occurred not with the infusion of Adenoscan but several hours after the infusion terminated. Also, 8.4% of the side effects that began coincident with the infusion persisted for up to 24 hours after the infusion was complete. In many cases, it is not possible to know whether these late adverse events are the result of Adenoscan infusion.

Flushing	44%	Gastrointestinal discomfort	13%	Second-degree AV block	3%
Chest discomfort	40%	Lightheadedness/dizziness	12%	Paresthesia	2%
Dyspnea or urge to breathe deeply	29%	Upper extremity discomfort	4%	Hypotension	2%
Headache	18%	ST segment depression	3%	Nervousness	2%
Throat, neck or jaw discomfort	15%	First-degree AV block	3%	Arrhythmias	1%

Adverse experiences of any severity reported in less than 1% of patients include:

Body as a Whole: back discomfort; lower extremity discomfort; weakness.

Cardiovascular System: nonfatal myocardial infarction; life-threatening ventricular arrhythmia; third-degree AV block; bradycardia; palpitation; sinus exit block; sinus pause; sweating; T-wave changes, hypertension (systolic blood pressure > 200 mm Hg).

Central Nervous System: drowsiness; emotional instability; tremors.

Genital/Urinary System: vaginal pressure; urgency.

Respiratory System: cough.

Special Senses: blurred vision; dry mouth; ear discomfort; metallic taste; nasal congestion; scotomas; tongue discomfort.

OVERDOSAGE:

The half-life of Adenosine is less than 10 seconds and side effects of Adenoscan (when they occur) usually resolve quickly when the infusion is discontinued, although delayed or persistent effects have been observed. Methylxanthines, such as caffeine and theophylline, are competitive adenosine receptor antagonists and theophylline has been used to effectively terminate persistent side effects. In controlled U.S. clinical trials, theophylline (50-125 mg slow intravenous injection) was needed to abort Adenoscan side effects in less than 2% of patients.

DOSAGE AND ADMINISTRATION:

For intravenous infusion only.

Adenoscan should be given as a continuous peripheral intravenous infusion.

The recommended intravenous dose for adults is 140 mcg/kg/min infused for six minutes (total dose of 0.84 mg/kg).

The required dose of thallium-201 should be injected at the midpoint of the Adenoscan infusion (i.e., after the first three minutes of Adenoscan). Thallium-201 is physically compatible with Adenoscan and may be injected directly into the Adenoscan infusion set.

The injection should be as close to the venous access as possible to prevent an inadvertent increase in the dose of Adenoscan (the contents of the IV tubing) being administered. There are no data on the safety or efficacy of alternative Adenoscan infusion protocols.

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

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

CAUTION: Federal law prohibits dispensing without prescription.

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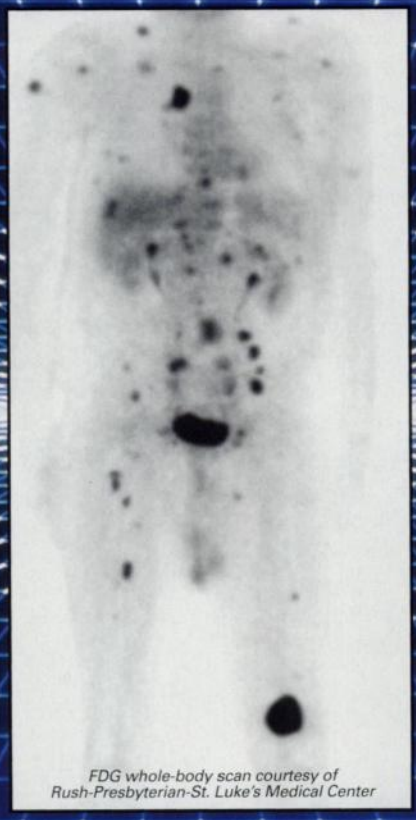
Research Triangle Park, NC 27709

Improving the Nuclear Medicine Image



FDG whole-body scan courtesy of Rush-Presbyterian-St. Luke's Medical Center

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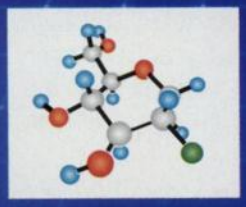

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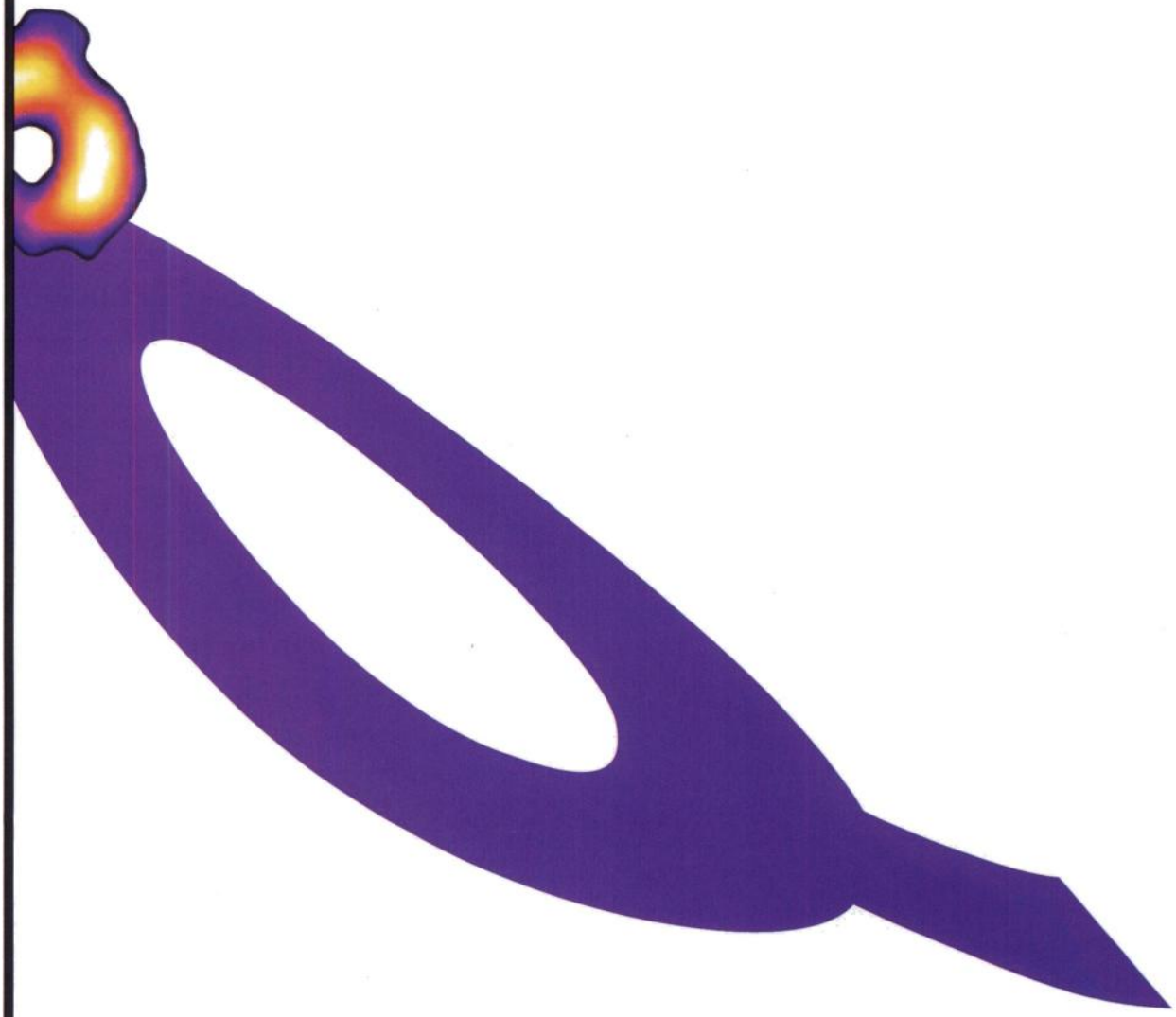
Please visit us at the SNM Annual Meeting • Booth 730 & 732

A SIGN OF THINGS TO COME IN CARDIAC IMAGING



MALLINCKRODT MEDICAL

SNM Annual Meeting Booth 111
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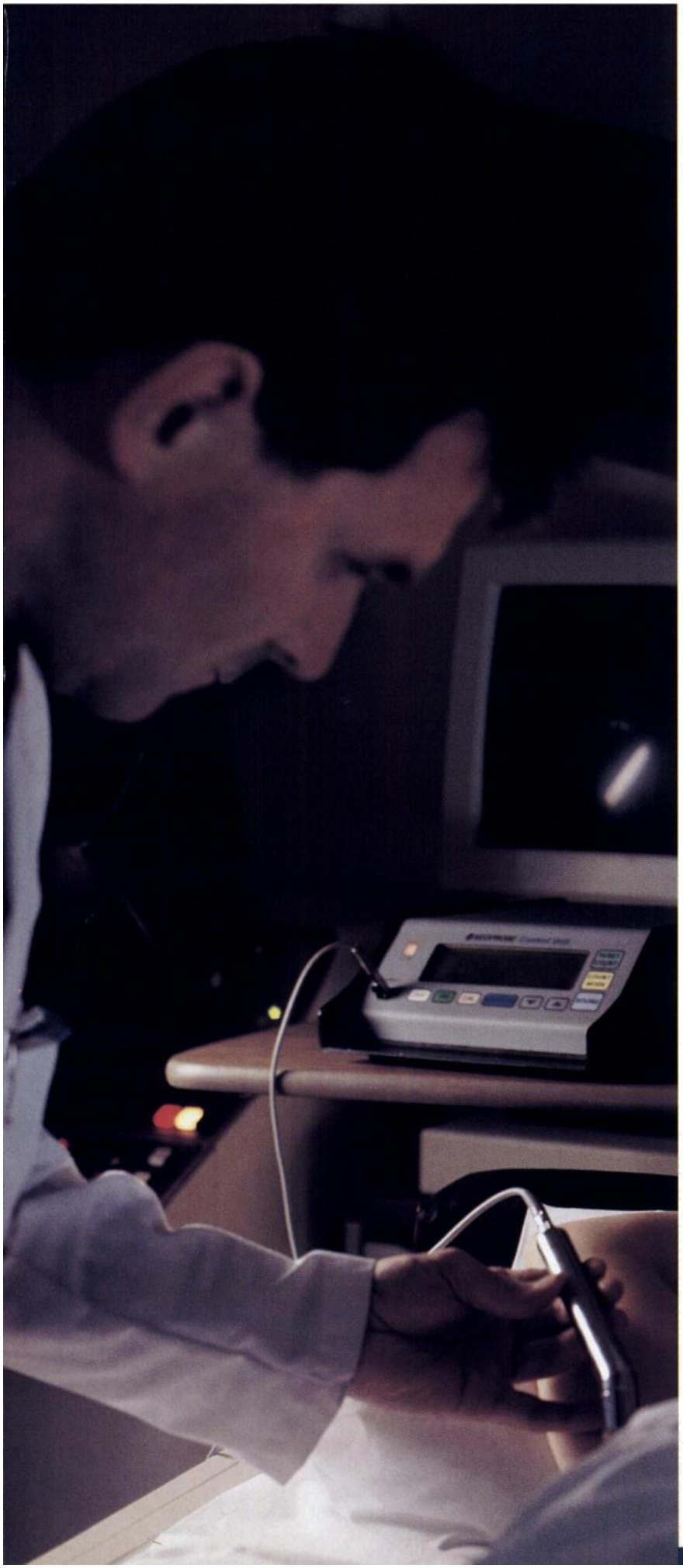

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*pending FDA approval

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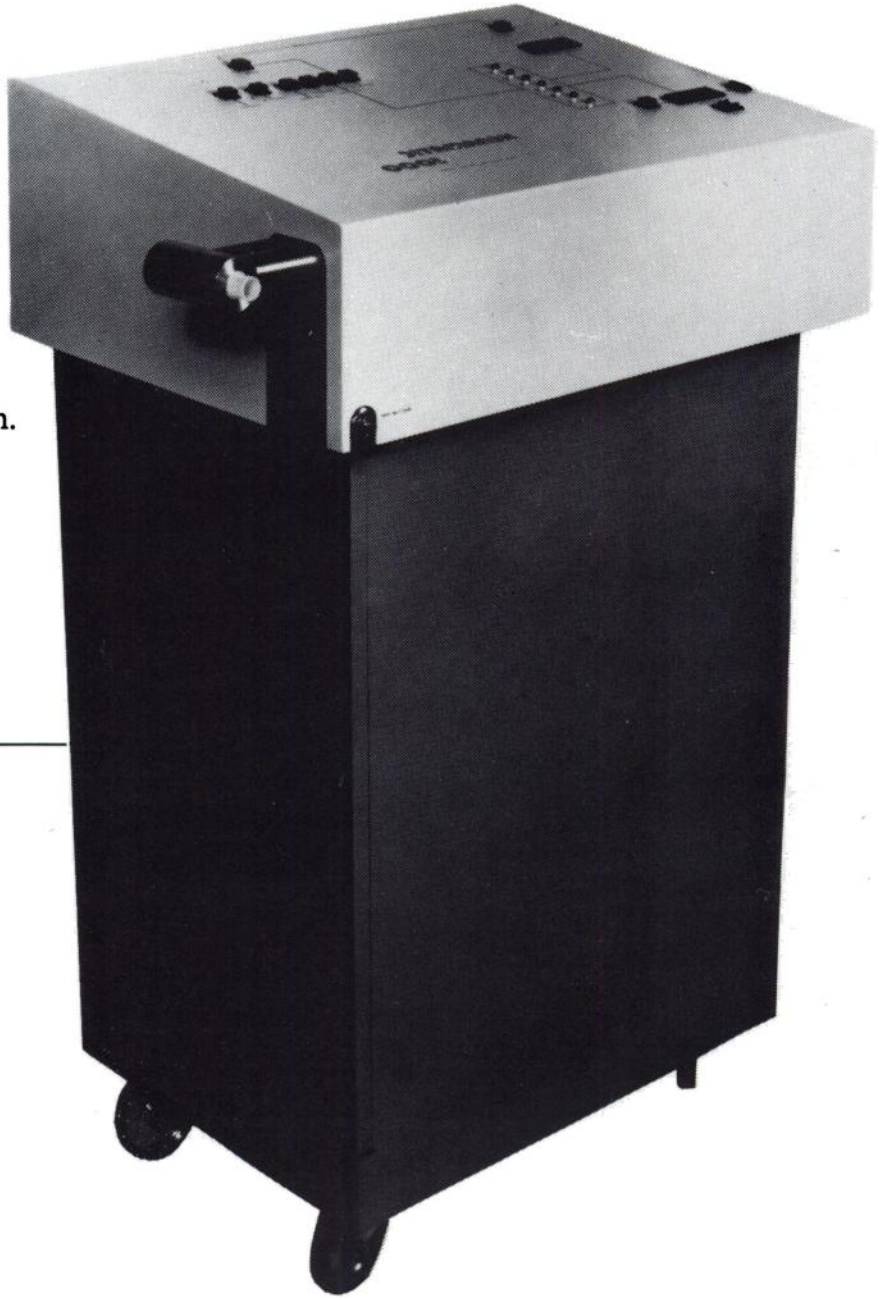

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SNM Annual Meeting Booths 426 and 428
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PROPOSED AMENDMENT TO REVISE THE SNM BYLAWS

ARTICLE XII, SECTION 1A

At its October 21-22, 1995 meeting, the Society of Nuclear Medicine (SNM) Board of Directors approved a motion to establish a new commission on radiopharmaceuticals, recognizing that this action would entail an amendment of Article XII, Section 1A, that is the addition of the following commission: "9. Commission on Radiopharmaceuticals."

In accord with the SNM Bylaws, Article XV, Section 3, regarding amendments to the Bylaws, the proposed amended Section is hereby published for the SNM Membership:

ARTICLE XII

COMMISSIONS AND COMMITTEES

Section 1: DESCRIPTION

A. The House of Delegates shall have the following Standing Commissions, as well as Subcommissions established, as circumstances warrant, to address professional, scientific, research, education and practice issues and Society programs:

(1) Commission on Chapters
(2) Commission on Councils
(3) Commission on Education
(4) Commission on Ethics
(5) Commission on Nominations, Bylaws & Organization
(6) Commission on Practice
(7) Commission on Health Care Policy
(8) Commission on Scientific Affairs & Research
(9) Commission on Radiopharmaceuticals

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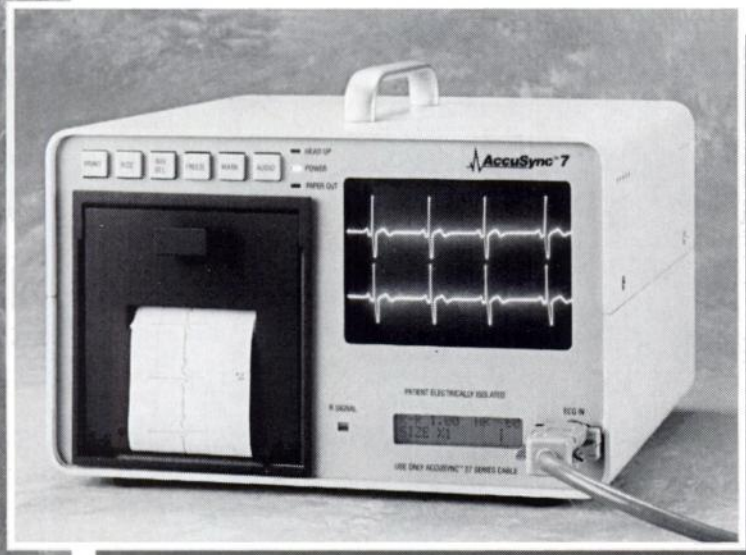

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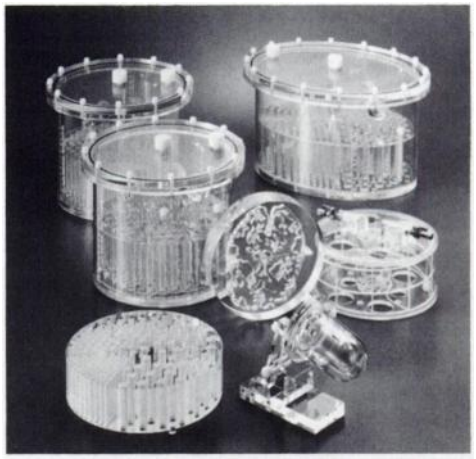

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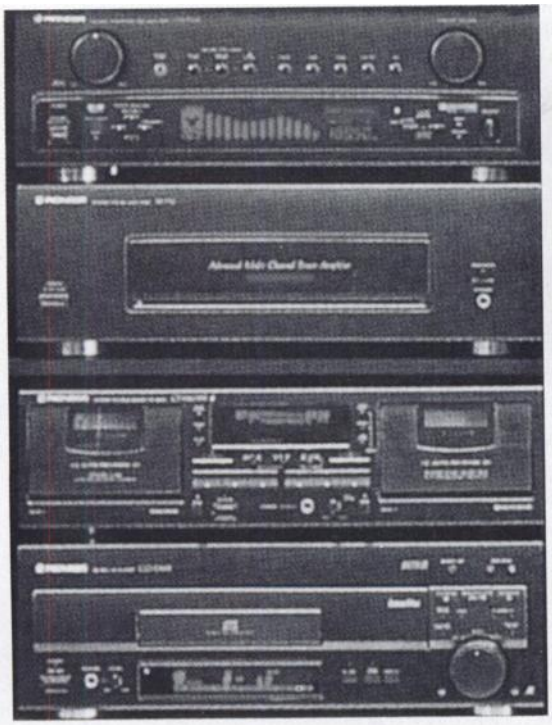
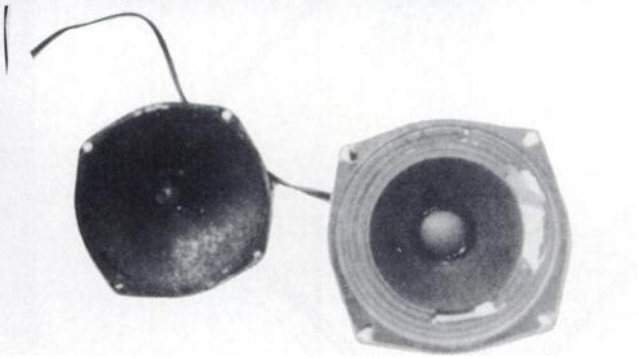


IF THIS IS YOUR GAMMA CAMERA WOULD YOU BE SATISFIED WITH THESE COLLIMATORS!



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Position Available

Division Chief of Nuclear Medicine

Peoria Radiology Associates seeks a board certified radiologist with specialty board certification in Nuclear Medicine. Responsibilities will include Division Chief of the Nuclear Medicine section and occasional coverage of CT, MRI, Sono and General Radiology. The successful candidate will be joining a group of 20 radiologists with a thriving practice in a large tertiary care hospital and surrounded by community hospitals. Resident and medical student teaching will be expected. Send CV and date of availability to Dr. G.T. Campbell, c/o Laura Lee, Peoria Radiology Associates, 530 N.E. Glen Oak Ave., Peoria, IL 61637.

Fellowships

Unexpected opening in Nuclear Medicine fellowship program beginning July 1996. One or two year program leading to board eligibility. Full range of education including PET, radiopharmaceutical therapy, pediatrics and opportunities to do research. Applicants should have completed two years of an approved residency program. Apply: David E. Kuhl, MD, Division of Nuclear Medicine, University of Michigan Medical Center, 1500 E. Medical Center Drive, Ann Arbor, MI 48109-0028. Phone: 313-936-5388, Fax: 313-936-8182.

Postdoctoral fellowships in neuroimaging are currently available at Yale University for research studies of patients with psychiatric illnesses. Yale's brain imaging group has world-renowned expertise and state-of-the-art facilities in several neuroimaging methodologies. The currently advertised fellowships will primarily use SPECT, PET and structural MRI. Applicants must have either an MD or PhD degree — with training related to neuroimaging being advantageous but not required. Must either have expertise in or be capable of readily learning computer analysis of imaging data. Send CV to: Robert B. Innis, MD, PhD, Dir. Neurochemical Brain Imaging Program, Yale University & VA Med. Ctr./116A2, 950 Campbell Ave., West Haven, CT 06516. EOE.

PET Technologist

The Henry M. Jackson Foundation for the Advancement of Military Medicine is seeking to hire a PET Technologist who will perform advanced computer-based PET imaging procedures on patients and experimental animals. Procedures include computer data acquisition and processing of brain and body PET scans using a wide variety of radiopharmaceuticals. Responsible for image reconstruction and display, scanner calibration, computer data transfer and archiving, and operation of ancillary PET laboratory equipment. Attention to detail and computer literacy required. Must be either CNMT or ARRT registered as a nuclear medicine technologist and a graduate of an accredited nuclear medicine program – no prior experience in PET is required. Heavy lifting of large equipment and incapacitated patients is done with the help of other employees. Will require flexible hours with possibility of some overtime. Interested individuals should submit a cover letter and resume to: Human Resources Dept., The Henry M. Jackson Foundation for the Advancement of Military Medicine, 1401 Rockville Pike, Suite 600, Rockville, MD 20852. Or e-mail at hr@mail.hjf.org AA/EOE

Postdoctoral Fellowship in PET Instrumentation

The Crump Institute for Biological Imaging has an immediate opening for a postdoctoral fellow in the field of PET instrumentation. The successful applicant will be part of a small team of investigators developing a dedicated high resolution PET system for animal imaging. Applicants should have experience in one or more of the following areas: nuclear instrumentation, gamma-ray detectors, data acquisition control, high speed electronics, detector simulation and image reconstruction. To apply, send CV and a description of relevant experience to: Simon R. Cherry, PhD, Crump Institute for Biological Imaging, UCLA School of Medicine, A-222A JLNRC, 700 Westwood Plaza, Los Angeles, CA 90095-1770. A more detailed description of the position is available on the internet at http://www.nuc.ucla.edu/html_docs/crump/ad/html

Registered and Certified Nuclear Medicine Technologist

A suburban central Pennsylvania cardiology practice is seeking a registered and certified nuclear medicine technologist to work full-time with two other full-time technologists in the operation of its nuclear cardiology department. This well-equipped department performs SPECT myocardial perfusion studies and gated cardiac blood pool scans. The emphasis here is placed on the quality of work, the well-being and comfort of our patients, and the safety of our employees. Experience with quantitative analysis and the use of personal computers would be beneficial, but we can train a well-qualified and motivated individual. Please send registries and certifications (including reg. and cert. numbers), schools attended, transcripts (if college graduate) and resume to: Associated Cardiologists, P.C., Attn: James P. Wallen, Nuclear Cardiology, 856 Century Drive, Mechanicsburg, PA 17055.

Research Assistant Professor

A Research Assistant Professor position in the area of in vivo CNS receptor imaging is available in the Department of Radiology, University of Pennsylvania. Candidates should have either a MD/PhD or MD degree with experience in in vivo imaging, neuropharmacology or related areas of neuroscience. Knowledge of tracer kinetics is helpful but not necessary. The scientist will participate as a team member developing I-123 and Tc-99m labeled tracers for functional imaging of CNS neuroreceptors with SPECT in animals and humans. A generous start-up package will be provided and the scientist is expected to develop extramural research support. Send resume to: Hank F. Kung, PhD, Department of Radiology, University of Pennsylvania, Philadelphia, 3400 Spruce Street, Philadelphia, PA 19104-4283. The University of Pennsylvania is an Equal Opportunity/Affirmative Action Employer.E-mail: kunghf@sunmac.spect.upenn.edu; http://sunmac.spect.upenn.edu

Position Wanted

Experience ABNM certified physician seeks FT job. Dr. Garcia, (914) 778-2601.

Board Certified NMT/Board Certified PA seeks position combining use of both skills. S. Koehler, PA-C, CNMT. 505-254-9543.

ABNM certified, young, energetic, experienced in all aspects of general nuclear medicine, including PET, seeking temporary/permanent, PT/FT job in a veterans affairs or state county hospital. Salary negotiable. Will take full responsibilities including coverage for vacation, meetings, calls, weekends, etc... Available to relocate. Beginning immediately. Please leave a message at 310-473-5137.

The Society of Nuclear Medicine (SNM) is incorporated in the State of Washington, as its primary State of incorporation. The State of Washington requires that limitations on the personal liability of directors be included in the Articles of Incorporation. This provision provides protection for directors and officers against claims from the Society or members but not against claims from third parties.

The SNM Articles of Incorporation state that they may be amended by a two-thirds vote of the membership present at a meeting called and held for that purpose, or may be amended by a vote of two-thirds of the members present and voting at any annual meeting, notice having been given to all members of such proposed amendment in writing at least thirty (30) days prior to such annual meeting.

While the SNM Board of Directors may, by resolution, indemnify directors and officers against claims arising from their conduct as such, but the Board also wishes to include in a resolution provisions which parallel the limitations on liability above, that is, which provide that the indemnification shall not eliminate or limit the liability of directors or officers for acts or omissions that involve intentional misconduct by them or a knowing violation of law, and unlawful distribution, or a benefit in money, property or services to which they are not legally entitled.

Accordingly, the Board of Directors at its January 12-13, 1996 meeting approved a motion to present the following motion at the 1996 SNM Annual Business Meeting for review and approval by the membership.

RESOLVED, that an additional article be added to the Articles of Incorporation of the Society of Nuclear Medicine (SNM) as Article VIII:

Article VIII

Limitation of Liability

The directors and officers of the Society shall have no personal liability for monetary damages to the Society or its members for their conduct as directors or officers, provided, that the liability of directors and officers shall not be limited for acts or omissions that involve intentional misconduct by them or a knowing violation of law, an unlawful distribution or a benefit in money, property or services to which they are not legally entitled.

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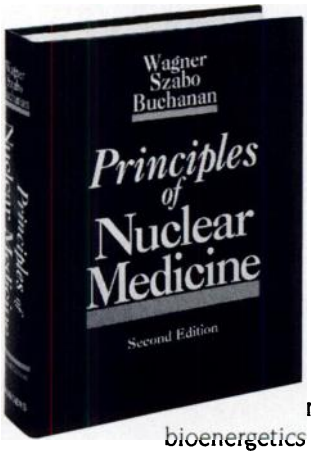

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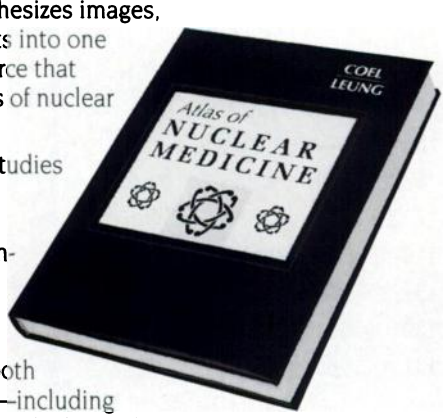

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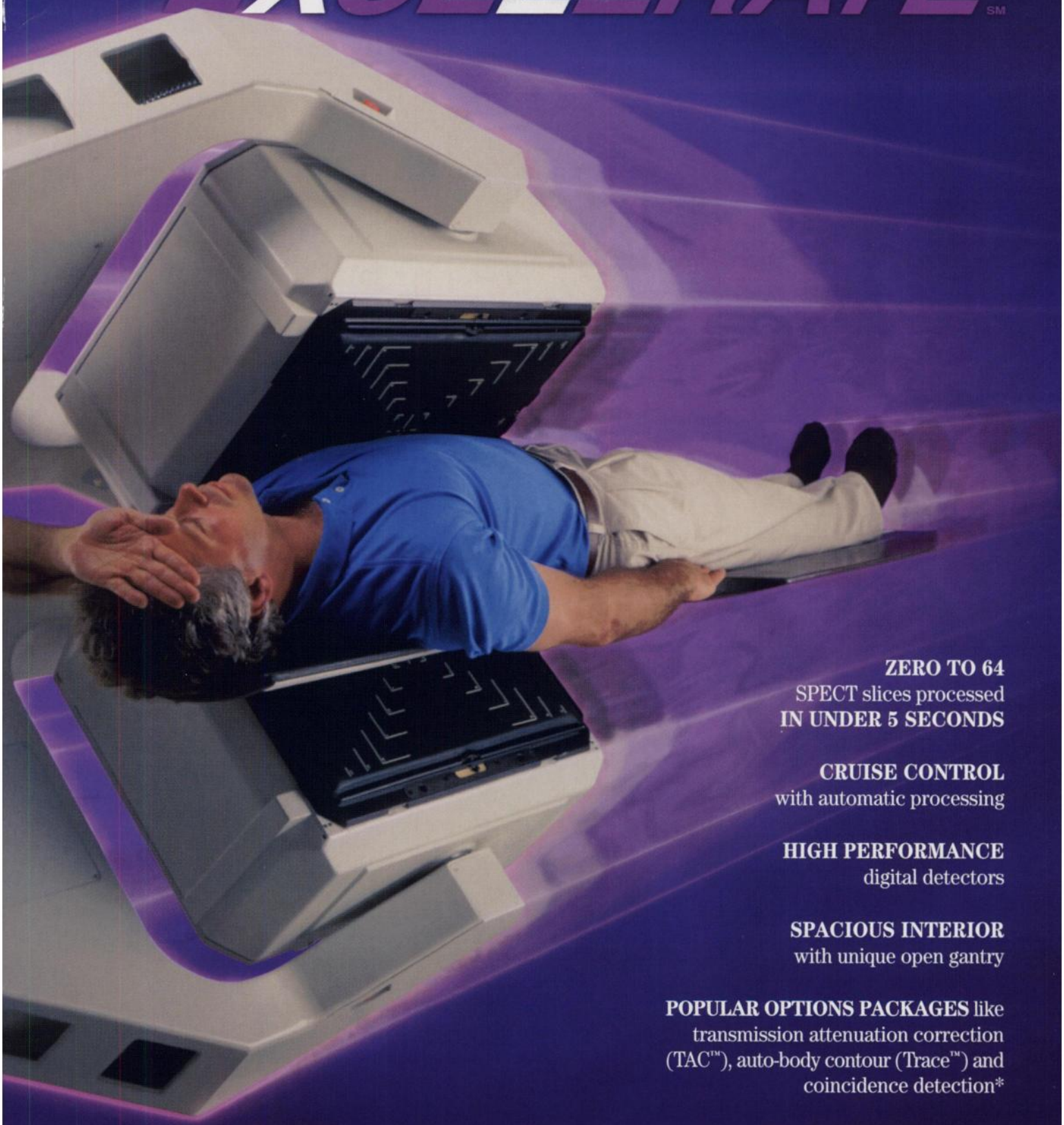

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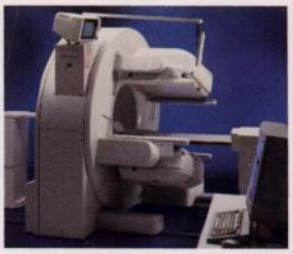

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