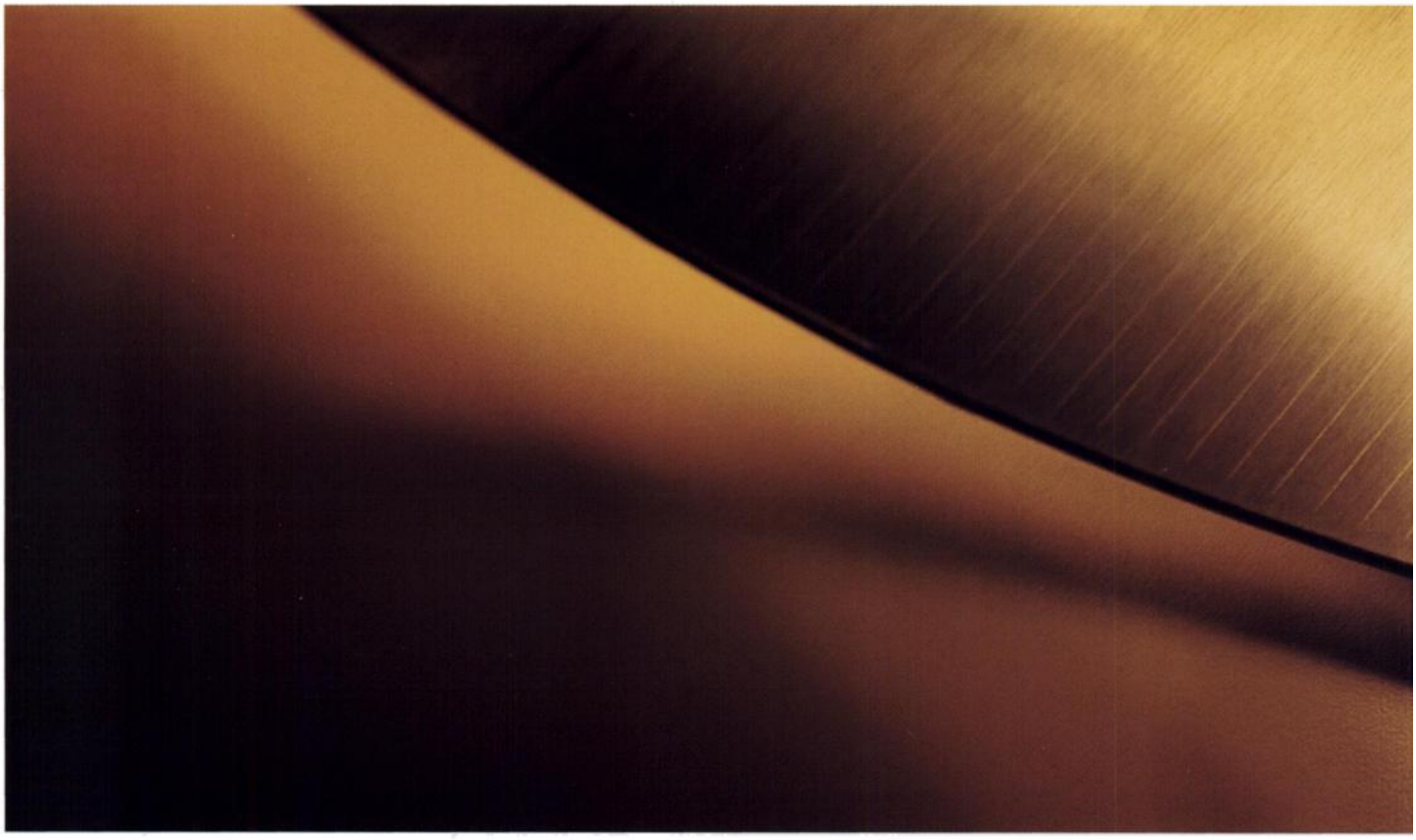
SIEMENS

No One Comes Closer.



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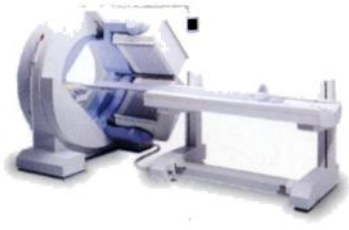
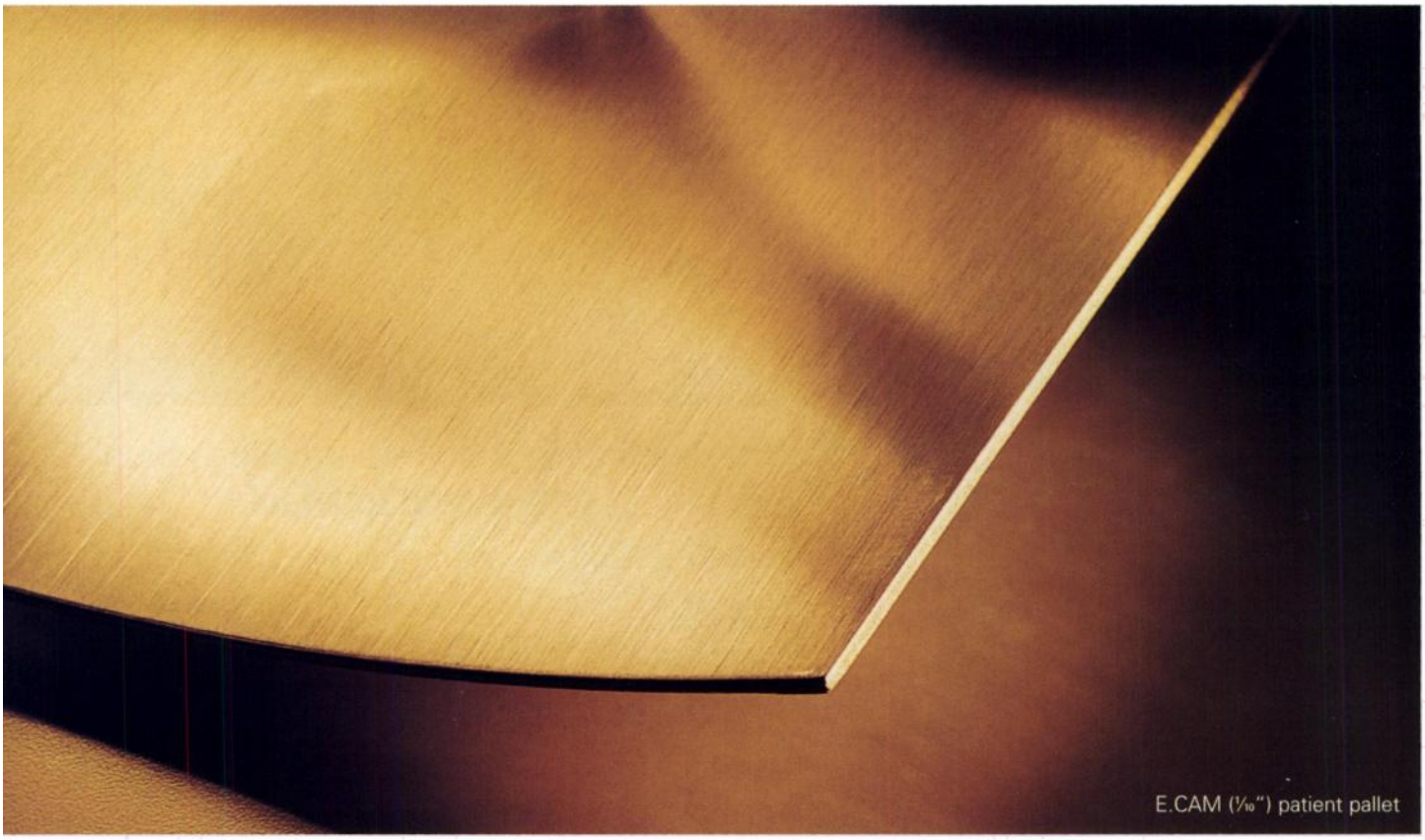
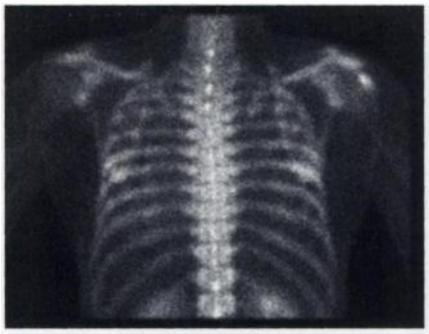
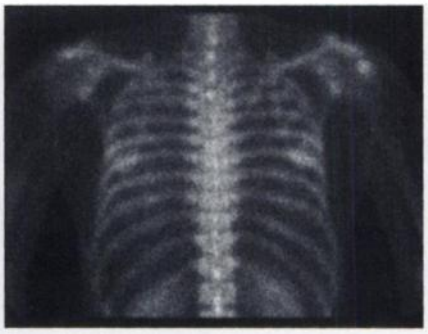






E.CAM™ ultra-thin patient pallet



Conventional carbon fiber pallet

If nuclear medicine is constantly changing, shouldn't your thyroid uptake system be able to keep up?

Imagine buying a thyroid uptake system that's built to last...and to adapt.

The CAPTUS® 2000 offers the most advanced capabilities from subtracting a predose measurement, counting a single capsule and multiplying by the number given, to measuring residual liquid activity in a vial after the dose is given. Design innovations such as the spring arm stand and automated constancy tests make it easier and faster to use.

But the most powerful advantage of the CAPTUS® 2000 is in its Intel® Pentium® Processor and familiar Microsoft Windows® based software. As new procedures are developed, they can be programmed into the software with the insertion of a disk. Introducing a new technique doesn't require a new equipment purchase.

The CAPTUS® 2000: built for high performance today...and tomorrow.

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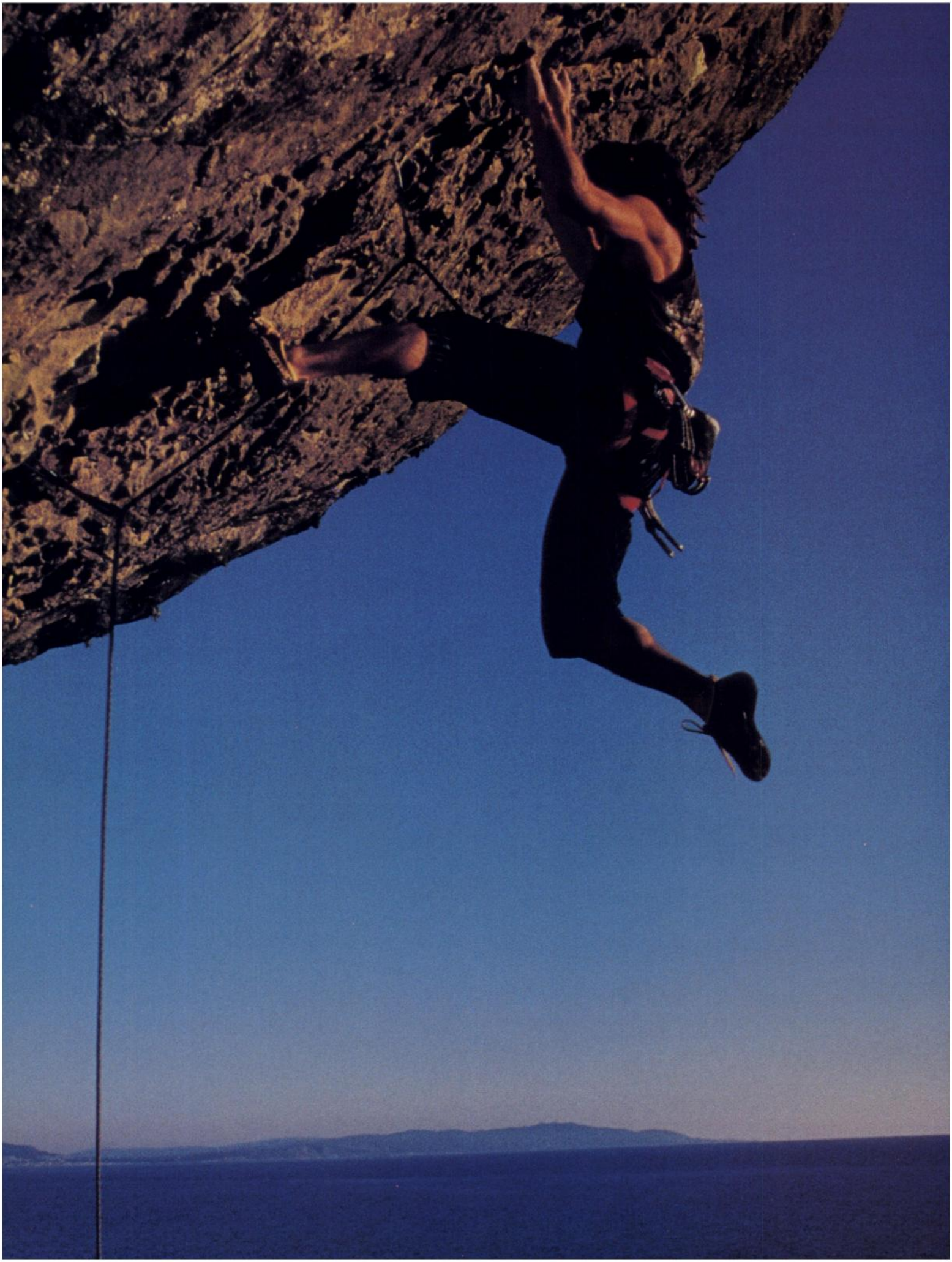
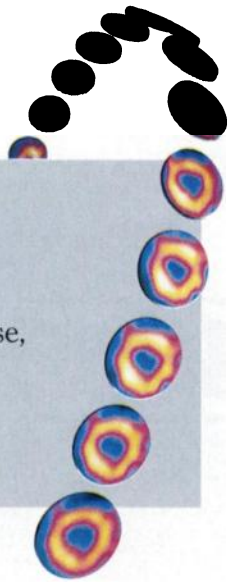


It's better under stress

The value of cardiac imaging lies in the accuracy of stress perfusion images. And that's where Cardiolite® comes through.

With Cardiolite, you can simultaneously obtain stress perfusion and resting function *(gated stress Cardiolite study)*—that's critical diagnostic information regarding cardiac perfusion, wall motion, wall thickening, and LVEF—all of which can help with patient management decisions. And, for patients unable to achieve adequate levels of stress through exercise, imaging results can be optimized by using pharmacologic agents such as I.V. Persantine® (dipyridamole USP).

To enhance patient management, find out about the advantages of stress Cardiolite before you order your next study.



By performing stress Cardiolite studies you can...

- Accurately diagnose CAD
- Risk stratify patients with known or suspected CAD
- Reduce equivocal interpretation in difficult-to-image patients (women, obese, and large-chested)
- Acquire stress perfusion and resting function information
- Improve patient management decisions, which may reduce costs

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

To reduce the uncertainty Cardiolite comes through

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. Pharmacologic stress may be associated with serious adverse events such as myocardial infarction, arrhythmias, hypertension, bronchoconstriction, and cerebrovascular events. Caution should be used when pharmacologic stress is selected as an alternative to exercise.

Persantine® is a registered trademark of Boehringer Ingelheim International GmbH. *I.V. Persantine*® is manufactured and distributed by DuPont Pharma under license from Boehringer Ingelheim Pharmaceuticals, Inc.

Please see brief summary of prescribing information on adjacent page.

Brief Summary

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

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

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

CONTRAINDICATIONS: None known.

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

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

PRECAUTIONS:

GENERAL

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

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

Contents of the kit before preparation are not radioactive. However, after the Sodium 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.

DU PONT PHARMA
Radiopharmaceuticals

Marketed by
DuPont Radiopharmaceutical Division
The DuPont Merck Pharmaceutical Co.
331 Treble Cove Road
Billerica, Massachusetts, USA 01862
For ordering Tel. Toll Free: 800-225-1572
All other business: 800-362-2668
(For Massachusetts and International, call 508-667-9531)

513121-0296 2/96 Printed in U.S.A.

I.V. PERSANTINE®

(dipyridamole USP) Injection 5mg/ml

Brief Summary of Prescribing Information

INDICATIONS AND USAGE IV Persantine® (dipyridamole USP) is indicated as an alternative to exercise in thallium myocardial perfusion imaging for the evaluation of coronary artery disease in patients who cannot exercise adequately.

CONTRAINDICATIONS Hypersensitivity to dipyridamole.

WARNINGS Serious adverse reactions associated with the administration of intravenous Persantine® (dipyridamole USP) have included cardiac death, fatal and non-fatal myocardial infarction, ventricular fibrillation, symptomatic ventricular tachycardia, stroke, transient cerebral ischemia, seizures, anaphylactoid reaction and bronchospasm. There have been reported cases of asystole, sinus node arrest, sinus node depression and conduction block. Patients with abnormalities of cardiac impulse formation/conduction or severe coronary artery disease may be at increased risk for these events.

In a study of 3911 patients given intravenous Persantine® as an adjunct to thallium myocardial perfusion imaging, two types of serious adverse events were reported: 1) four cases of myocardial infarction (0.1%), two fatal (0.05%), and two non-fatal (0.05%); and 2) six cases of severe bronchospasm (0.2%). Although the incidence of these serious adverse events was small (0.3%, 10 of 3911), the potential clinical information to be gained through use of intravenous Persantine® thallium imaging must be weighed against the risk to the patient. Patients with a history of unstable angina may be at a greater risk for severe myocardial ischemia. Patients with a history of asthma may be at a greater risk for bronchospasm during IV Persantine® use.

When thallium myocardial perfusion imaging is performed with intravenous Persantine®, parenteral aminophylline should be readily available for relieving adverse events such as bronchospasm or chest pain. Vital signs should be monitored during, and for 10-15 minutes following, the intravenous infusion of Persantine® and an electrocardiographic tracing should be obtained using at least one chest lead. Should severe chest pain or bronchospasm occur, parenteral aminophylline may be administered by slow intravenous injection (50-100 mg over 30-60 seconds) in doses ranging from 50 to 250 mg. In the case of severe hypotension, the patient should be placed in a supine position with the head tilted down if necessary, before administration of parenteral aminophylline. If 250 mg of aminophylline does not relieve chest pain symptoms within a few minutes, sublingual nitroglycerin may be administered. If chest pain continues despite use of aminophylline and nitroglycerin, the possibility of myocardial infarction should be considered. If the clinical condition of a patient with an adverse event permits a one minute delay in the administration of parenteral aminophylline, thallium-201 may be injected and allowed to circulate for one minute before the injection of aminophylline. This will allow initial thallium perfusion imaging to be performed before reversal of the pharmacologic effects of Persantine® on the coronary circulation.

PRECAUTIONS See WARNINGS

Drug Interactions Oral maintenance theophylline and other xanthine derivatives such as caffeine may abolish the coronary vasodilatation induced by intravenous Persantine® (dipyridamole USP) administration. This could lead to a false negative thallium imaging result (see Mechanism of Action).

Myasthenia gravis patients receiving therapy with cholinesterase inhibitors may experience worsening of their disease in the presence of dipyridamole.

Carcinogenesis, Mutagenesis, Impairment of Fertility In studies in which dipyridamole was administered in the feed at doses of up to 75 mg/kg/day (9.4 times* the maximum recommended daily human oral dose) in mice (up to 128 weeks in males and up to 142 weeks in females) and rats (up to 111 weeks in males and females), there was no evidence of drug related carcinogenesis. Mutagenicity tests of dipyridamole with bacterial and mammalian cell systems were negative. There was no evidence of impaired fertility when dipyridamole was administered to male and female rats at oral doses up to 500 mg/kg/day (63 times* the maximum recommended daily human oral dose). A significant reduction in number of corpora lutea with consequent reduction in implantations and live fetuses was, however, observed at 1250 mg/kg/day.

*Calculation based on assumed body weight of 50 kg.

Pregnancy Category B Reproduction studies performed in mice and rats at daily oral doses of up to 125 mg/kg (15.6 times* the maximum recommended daily human oral dose) and in rabbits at daily oral doses of up to 20 mg/kg (2.5 times* the maximum recommended daily human oral dose) have revealed no evidence of impaired embryonic development due to dipyridamole. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human responses, this drug should be used during pregnancy only if clearly needed.

*Calculation based on assumed body weight of 50 kg.

Nursing Mothers Dipyridamole is excreted in human milk.

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

ADVERSE REACTIONS Adverse reaction information concerning intravenous Persantine® (dipyridamole USP) is derived from a study of 3911 patients in which intravenous Persantine® was used as an adjunct to thallium myocardial perfusion imaging and from spontaneous reports of adverse reactions and the published literature.

Serious adverse events (cardiac death, fatal and non-fatal myocardial infarction, ventricular fibrillation, asystole, sinus node arrest, symptomatic ventricular tachycardia, stroke, transient cerebral ischemia, seizures, anaphylactoid reaction and bronchospasm.) are described above (see WARNINGS).

In the study of 3911 patients, the most frequent adverse reactions were: chest pain/angina pectoris (19.7%), electrocardiographic changes (most commonly ST-T changes) (15.9%), headache (12.2%), and dizziness (11.8%).

Drug-related adverse events occurring with >1% incidence in this study were: chest pain/angina pectoris (19.7%), headache (12.2%), dizziness (11.8%), electrocardiographic abnormalities/ST-T changes (7.5%), electrocardiographic abnormalities/extrasystoles (5.2%), hypotension (4.6%), nausea (4.6%), flushing (3.4%), electrocardiographic abnormalities/tachycardia (3.2%), dyspnea (2.6%), pain unspecified (2.6%), blood pressure lability (1.6%), hypertension (1.5%), paresthesia (1.3%), and fatigue (1.2%).

Less common adverse reactions occurring in 1% or less of the patients within the study included:

Cardiovascular System: Electrocardiographic abnormalities unspecified (0.8%), arrhythmia unspecified (0.6%), palpitation (0.3%), ventricular tachycardia (0.2% see WARNINGS), bradycardia (0.2%), myocardial infarction (0.1% see WARNINGS), AV block (0.1%), syncope (0.1%), orthostatic hypotension (0.1%), atrial fibrillation (0.1%), supraventricular tachycardia (0.1%), ventricular arrhythmia unspecified (0.03% see WARNINGS), heart block unspecified (0.03%), cardiomyopathy (0.03%), edema (0.03%).

Central and Peripheral Nervous System: Hypothesia (0.5%), hypertonia (0.3%), nervousness/anxiety (0.2%), tremor (0.1%), abnormal coordination (0.03%), somnolence (0.03%), dysphonia (0.03%), migraine (0.03%), vertigo (0.03%).

Gastrointestinal System: Dyspepsia (1.0%), dry mouth (0.8%), abdominal pain (0.7%), flatulence (0.6%), vomiting (0.4%), eructation (0.1%), dysphagia (0.03%), tenesmus (0.03%), appetite increased (0.03%).

Respiratory System: Pharyngitis (0.3%), bronchospasm (0.2% see WARNINGS), hyperventilation (0.1%), rhinitis (0.1%), coughing (0.03%), pleural pain (0.03%).

Other: Myalgia (0.9%), back pain (0.6%), injection site reaction unspecified (0.4%), diaphoresis (0.4%), asthenia (0.3%), malaise (0.3%), arthralgia (0.3%), injection site pain (0.1%), rigor (0.1%), earache (0.1%), tinnitus (0.1%), vision abnormalities unspecified (0.1%), dysgeusia (0.1%), thirst (0.03%), depersonalization (0.03%), eye pain (0.03%), renal pain (0.03%), perineal pain (0.03%), breast pain (0.03%), intermittent claudication (0.03%), leg cramping (0.03%). In additional postmarketing experience, there have been rare reports of allergic reaction including urticaria, pruritus, dermatitis and rash.

DU PONT PHARMA
Radiopharmaceuticals

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The DuPont Merck Pharmaceutical Co.
Billerica, MA 01862

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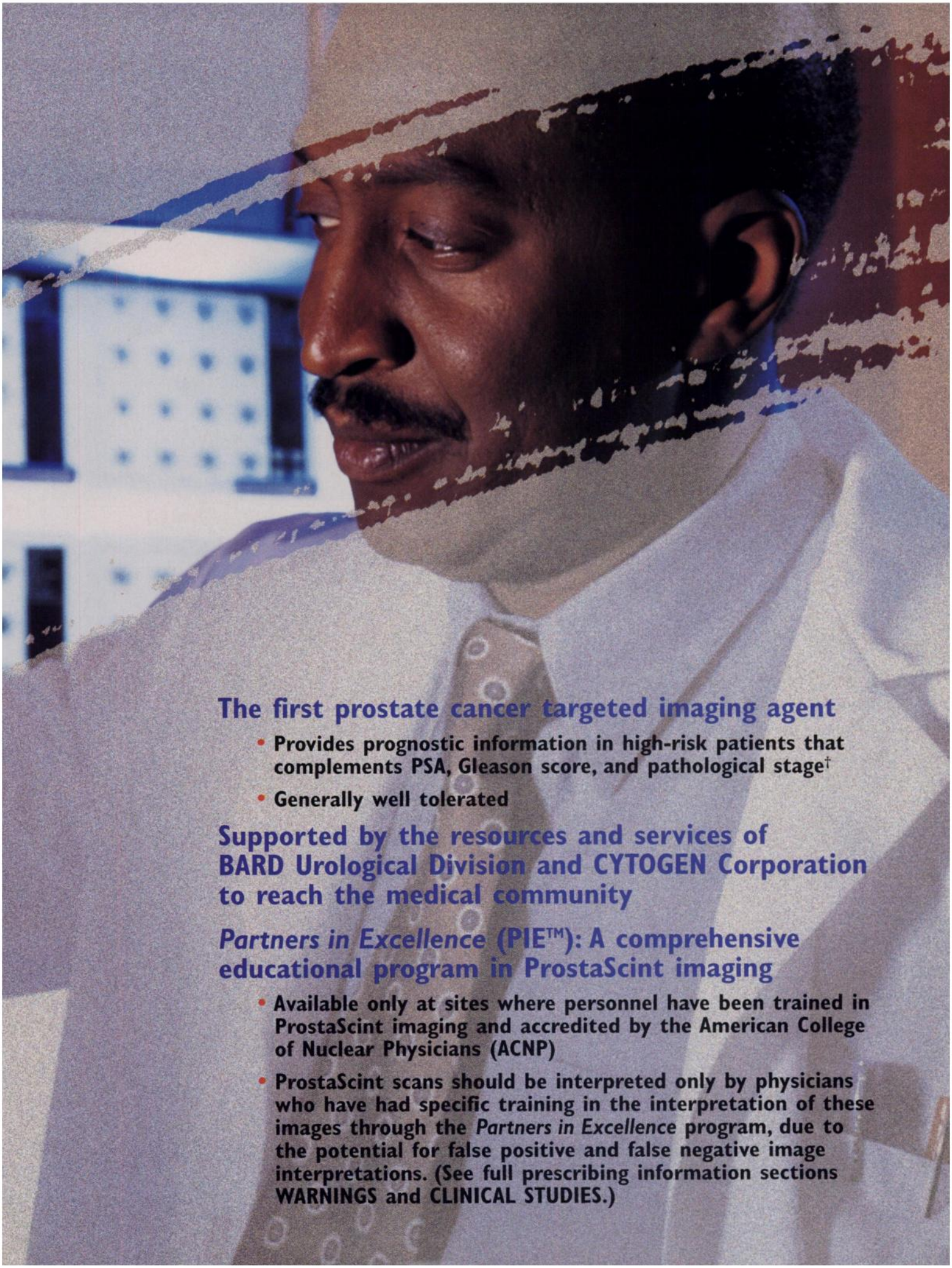

The first prostate cancer targeted imaging agent

- Provides prognostic information in high-risk patients that complements PSA, Gleason score, and pathological stage†
- Generally well tolerated

Supported by the resources and services of BARD Urological Division and CYTOGEN Corporation to reach the medical community

Partners in Excellence (PIE™): A comprehensive educational program in ProstaScint imaging

- Available only at sites where personnel have been trained in ProstaScint imaging and accredited by the American College of Nuclear Physicians (ACNP)
- ProstaScint scans should be interpreted only by physicians who have had specific training in the interpretation of these images through the *Partners in Excellence* program, due to the potential for false positive and false negative image interpretations. (See full prescribing information sections WARNINGS and CLINICAL STUDIES.)

ProstaScint™ Kit (Capromab Pendetide)

Kit for the Preparation of Indium In 111 Capromab Pendetide
For Intravenous Use Only

BRIEF SUMMARY–Consult package insert for full prescribing information

INDICATIONS AND USAGE Indium In 111 ProstaScint™ (Capromab Pendetide) is indicated as a diagnostic imaging agent in newly-diagnosed patients with biopsy-proven prostate cancer, thought to be clinically-localized after standard diagnostic evaluation (e.g. chest x-ray, bone scan, CT scan, or MRI), who are at high-risk for pelvic lymph node metastases (see CLINICAL PHARMACOLOGY, Imaging Performance in Newly-Diagnosed Patients). It is not indicated in patients who are not at high risk. Indium In 111 ProstaScint™ is also indicated as a diagnostic imaging agent in post-prostatectomy patients with a rising PSA and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease. The imaging performance of Indium In 111 ProstaScint™ following radiation therapy has not been studied. The information provided by Indium In 111 ProstaScint™ imaging should be considered in conjunction with other diagnostic information. Scans that are positive for metastatic disease should be confirmed histologically in patients who are otherwise candidates for surgery or radiation therapy unless medically contraindicated. Scans that are negative for metastatic disease should not be used in lieu of histological confirmation. ProstaScint™ is not indicated as a screening tool for carcinoma of the prostate nor for readministration for the purpose of assessment of response to treatment.

CONTRAINDICATIONS Indium In 111 ProstaScint™ 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 Patient management should not be based on Indium In 111 ProstaScint™ (Capromab Pendetide) scan results without appropriate confirmatory studies since in the pivotal trials, there was a high rate of false positive and false negative image interpretations (See PRECAUTIONS). Indium In 111 ProstaScint™ images should be interpreted only by physicians who have had specific training in Indium In 111 ProstaScint™ image interpretation (see PRECAUTIONS, Imaging Precautions). 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 Indium In 111 ProstaScint™ administration, medications for the treatment of hypersensitivity reactions should be available during administration of this agent. Indium In 111 ProstaScint™ may induce human anti-mouse antibodies which may interfere with some immunoassays, including those used to assay PSA and digoxin (see PRECAUTIONS, Drug/Laboratory Test Interactions).

PRECAUTIONS

General There were high rates of false positive and false negative image interpretations in the pivotal trials (see Clinical Studies). False positive scan interpretations may result in: (1) inappropriate surgical intervention to confirm scan results; (2) inappropriate denial of curative therapy if results are not confirmed; or (3) inadequate surgical staging if only areas of uptake are sampled. Surgical sampling should not be limited to the areas of positive uptake, unless histologic examination of these areas is diagnostic. Due to the potential for false negative scan interpretations, negative images should not be used in lieu of histologic confirmation. Proper patient preparation is mandatory to obtain optimal images for interpretation (see Imaging Precautions, below). Bone scans are more sensitive than ProstaScint™ (Capromab Pendetide) for the detection of metastases to bone, and Indium In 111 ProstaScint™ should not replace bone scan for the evaluation of skeletal metastases.

Imaging Precautions 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. Indium In 111 ProstaScint™ images should be interpreted only by physicians who have had specific training in the interpretation of Indium In 111 ProstaScint™ images. There may be Indium In 111 ProstaScint™ clearance and imaging localization observed in the bowel, blood pool, kidneys, and urinary bladder. When obtaining all 72-120 hour planar and Single-Photon Emission Computed Tomography (SPECT) images, the bladder should be catheterized and irrigated. The administration of a cathartic is required the evening before imaging the patient, and a cleansing enema should be administered within an hour prior to each 72-120 hour imaging session. The contents of the kit are not radioactive. However, after the Indium In 111 chloride is added, appropriate shielding of Indium In 111 ProstaScint™ must be maintained. Care should be taken to minimize radiation exposure to patients and medical personnel, consistent with proper hospital and patient management procedures. Each ProstaScint™ kit is a unit of use package. The contents of the kit are to be used only to prepare Indium In 111 ProstaScint™; unlabeled ProstaScint™ should NOT be administered directly to the patient. After radiolabeling with Indium In 111, the entire Indium In 111 ProstaScint™ dose must be administered to the patient for whom it was prescribed. Reducing the dose of Indium In 111, unlabeled ProstaScint™, or Indium In 111 ProstaScint™ may adversely impact imaging results and is not recommended. The components of the kit are sterile and pyrogen-free and contain no preservative. Indium In 111 ProstaScint™ 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.

Information for Patients Murine monoclonal antibodies (MAbs) are foreign proteins, and their administration can induce HAMA. While limited data exist concerning the clinical significance of HAMA, the presence of HAMA may interfere with murine-antibody based immunoassays, or could compromise the efficacy of diagnostic or therapeutic murine antibody-based agents and increase the risk of adverse reactions. For these reasons, patients should be informed that the use of this product could adversely affect the future ability to diagnose recurrence of their tumor, the ability to perform certain other laboratory tests, or to use other murine-based products. Patients should be advised to discuss prior use of murine-antibody based products with their physicians (see Heterologous Protein Administration, below).

Heterologous Protein Administration Indium In 111 ProstaScint™ has been shown to induce HAMA to murine IgG infrequently and with low peak levels after single administration. HAMA levels were detected (at >8 ng/ml) by RIA after single infusion in 8% (20/239) of patients, while 1% of patients had levels greater than 100 ng/ml. In addition, serum HAMA levels were detected by RIA after repeat infusion in 19% (5/27) of the patients. While limited data exist concerning the clinical significance of HAMA, detectable serum levels can alter the clearance and tissue biodistribution of MAbs. The development of persistently elevated serum HAMA levels could compromise the efficacy of diagnostic or therapeutic murine antibody-based agents. In repeat administration trials, 93% (65/70) of the evaluable repeat infusions were associated with normal tissue distribution of the MAb conjugate. Pre-infusion serum HAMA levels were generally not predictive of altered distribution. When considering the administration of Indium In 111 ProstaScint™ to patients who have previously received other murine antibody-based products, physicians should be aware of the potential for assay interference and increased clearance and altered biodistribution, which may interfere with the quality or sensitivity of the imaging study. Prior to administration of murine antibodies, including Indium In 111 ProstaScint™, the physician should review the patient history to determine whether the patient has previously received such products.

Drug Interactions The effect of surgical and/or medical androgen ablation on the imaging performance of Indium In 111 ProstaScint™ has not been studied. Preliminary data suggest hormone ablation may increase PSMA expression, with concurrent decrease in tumor expression of PSA.[1] The use of ProstaScint™ in this patient population cannot be recommended at this time.

Drug/Laboratory Test Interactions The presence of HAMA in serum as a result of ProstaScint™ may interfere with some antibody-based immunoassays (such as PSA and digoxin). When present, this interference generally results in falsely high values. When following PSA levels, assay methods resistant to HAMA interference should be utilized. PSA assays which were found to be resistant to HAMA interference were Hybritech Tandem-R and Abbott IMX. When patients have received Indium In 111 ProstaScint™, the clinical laboratory should be notified to take appropriate measures to avoid interference by HAMA with clinical laboratory testing procedures. These methods include the use of non-murine-based immunoassays, HAMA removal by adsorption, or sample pre-treatment to block HAMA activity.

Carcinogenesis, Mutagenesis, Impairment of Fertility Long-term animal studies have not been performed to evaluate the carcinogenic or mutagenic potential of Indium In 111 ProstaScint™ or to evaluate its effect on fertility.

Pregnancy ProstaScint™ is not indicated for use in women.

Nursing Mothers and/or Lactating Women ProstaScint™ is not indicated for use in women.

Pediatric Use The safety and effectiveness of Indium In 111 ProstaScint™ in pediatric patients have not been established. ProstaScint™ is not indicated for use in children.

ADVERSE REACTIONS ProstaScint™ (Capromab Pendetide) was generally well tolerated in the clinical trials. After administration of 529 single doses of Indium In 111 ProstaScint™, adverse reactions were observed in 4% of patients. The most commonly reported adverse reactions were increases in bilirubin, hypotension, and hypertension, which occurred in 1% of patients. Elevated liver enzymes and injection site reactions occurred in slightly less than 1% of patients. Other adverse reactions, listed in order of decreasing frequency, were: pruritus, fever, rash, headache, myalgia, asthenia, burning sensation in thigh, shortness of breath, and alteration of taste. Most adverse reactions were mild and readily reversible. Data from repeat administration in 61 patients revealed a similar incidence of adverse reactions (5%). No deaths were attributable to Indium In 111 ProstaScint™ administration.

REFERENCE 1. Wright, GL, Jr; et al. Expression of Prostate-Specific Membrane Antigen in Normal, Benign, and Malignant Prostate Tissues. *Urol Oncol.* 1995; 1:18-28.

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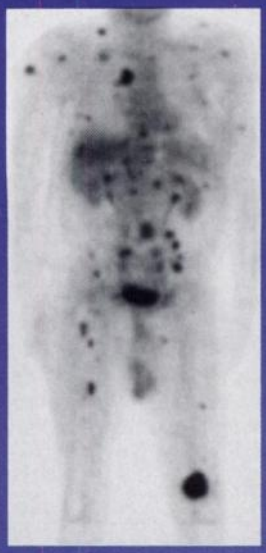

PET Image of
metastatic disease

Moderators:
Peter E. Valk, M.D. and
Michael E. Phelps, Ph.D.

INSTITUTE FOR
CLINICAL PET

Positron Imaging in Clinical Oncology

ICP/SNM Seminar

Tuesday, June 3, 1997 5:00-8:00 pm
Hilton Palacio del Rio
200 South Alamo Street
San Antonio, Texas

Course Outline

Imaging instrumentation, radiopharmaceutical delivery, clinical applications and reimbursement for positron imaging are rapidly changing. This course will provide an up-to-date perspective on the expansion of positron imaging technologies to include high energy collimation, dual head gamma cameras with coincidence detection, partial ring PET scanners and high end PET systems. The components of a radiopharmacy network that supplies FDG to clinics will be described. The clinical questions will be exemplified in the course by focusing on detection, staging and therapeutic assessment of various cancers with these positron imaging systems. Data from clinical trials, formulated into evidence based cost benefit analysis, will be presented along with an update on the status of reimbursement from various types of private and federal sources.

Program

5:00-5:05	Welcome	Peter E. Valk, M.D.
5:05-5:25	Positron Imaging Technology – Present and Future	Michael E. Phelps, Ph.D.
5:25-6:25	PET Imaging in Clinical Oncology	
	Solitary Pulmonary Nodules and Non-Small Cell Lung Cancer	R. Edward Coleman, M.D.
	Recurrent Colorectal Cancer	Peter E. Valk, M.D
	Metastatic Melanoma	Richard L. Wahl, M.D.
	Breast Cancer and Lymphoma	Carter Young, M.D.
	Head and Neck Cancer and Cancer of the Esophagus	Val J. Lowe, M.D.
6:25-6:40	BREAK	
6:40-7:10	Scintillation Camera FDG Imaging in Oncology	
	Cancer of the Lung and Colon	Martin P. Sandler, M.D.
	Cancer of the Lung, Esophagus and Head and Neck	Paul D. Shreve, M.D.
7:10-7:20	Availability and Delivery of FDG	Bradley Holmgren
7:20-7:35	Cost Benefit Analysis for Oncological Positron Imaging	Sanjiv S. Gambhir, M.D., Ph.D.
7:35-7:45	Reimbursement for Oncological Positron Imaging	Ruth Dean Tesar
7:45-8:00	Discussion	

Society of Nuclear Medicine

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Continuing Education Courses Refresher and state-of-the art continuing education courses in chemistry, physics, quality assurance, cardiovascular nuclear medicine, PET, SPECT and NMR will supply up-to-the minute approaches and procedures for all clinical settings.

Scientific Papers This year's presentation of over 1200 scientific papers and posters includes a distillation of the latest advancements and finest work achieved by outstanding scientists and physicians in the field of nuclear medicine. These papers, presented by the original authors, with over 30 subjects to choose from, will provide a unique opportunity for enhancing your knowledge or exploring new avenues in correlative areas of nuclear medicine. Ample time is allotted at these presentations for questions and discussions. An extensive display of scientific posters and exhibits will augment the presentations.

The ever-increasing importance of the role of nuclear medicine technologist will be explored in our Technologist Program, and over 150 hours of clinical updates will provide chief and staff technologists with the latest in basic, intermediate and advanced studies. This program will broaden expertise and enhance the technologist's contribution to nuclear medicine.

Exhibit All the major manufacturers of nuclear medicine products and services, more than 100 in all, will be on hand to explain and demonstrate the most technologically advanced equipment. Several companies will present User Meetings to give an in-depth understanding of their products.

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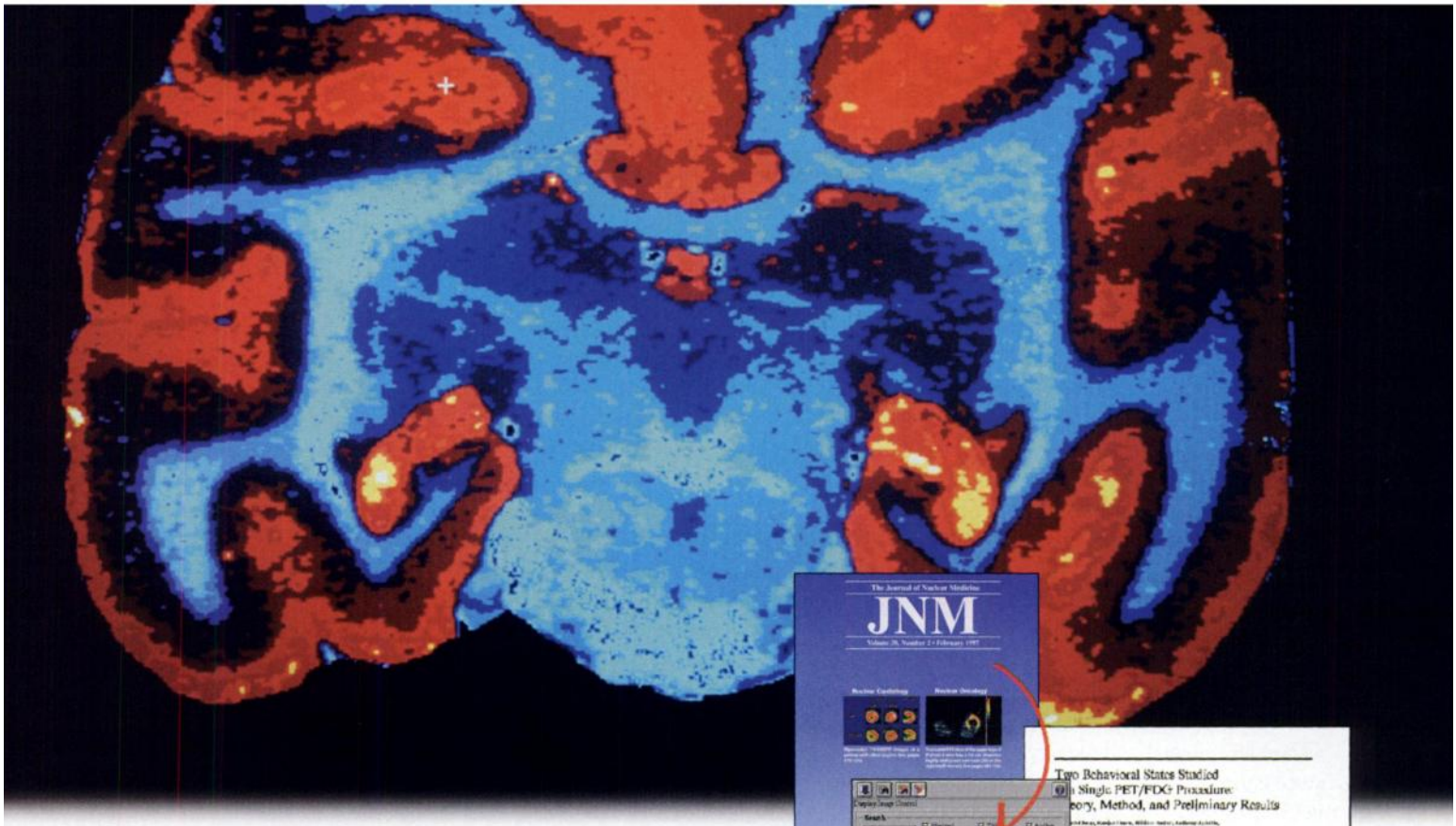

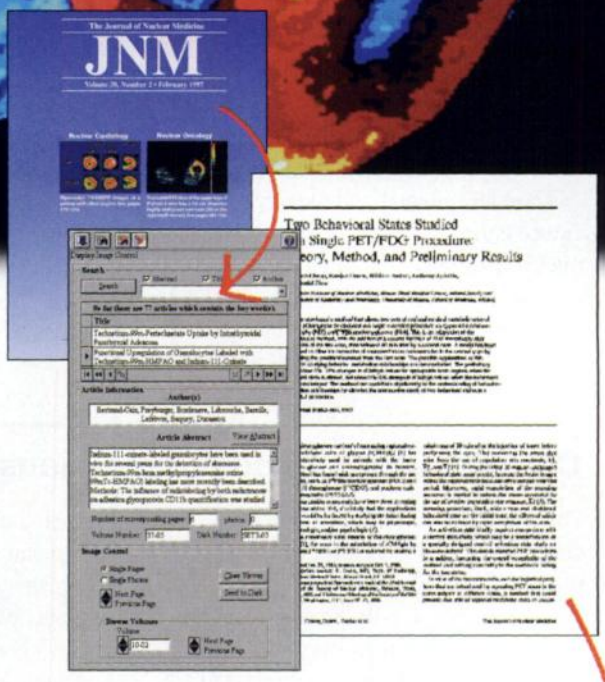

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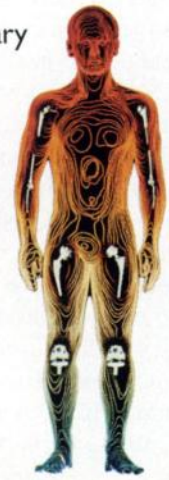

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- Low-radiation exposure compared to other myocardial perfusion agents
- Less than 1% of patients experienced side effects in clinical trials of 764 adults.

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See brief summary of prescribing information on 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 8.61×10^{-3} mSv/MBq and 1.12×10^{-2} mSv/MBq after exercise and rest respectively.

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

Distributed by: Medi-Physics, Inc., Amersham Healthcare
2636 S. Clearbrook Dr., Arlington Heights, IL 60005
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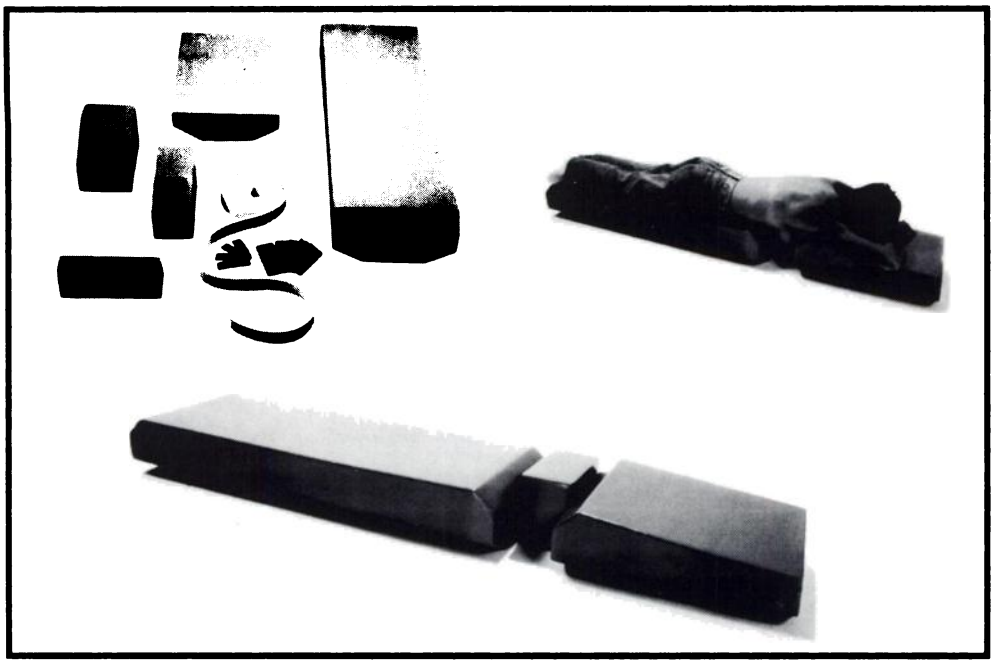

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For Spanish-speaking patients, *Guidelines for Patients Receiving Radioiodine Treatment* is available in Spanish. Look for other Spanish-language SNM Patient Pamphlet titles appearing in 1997.

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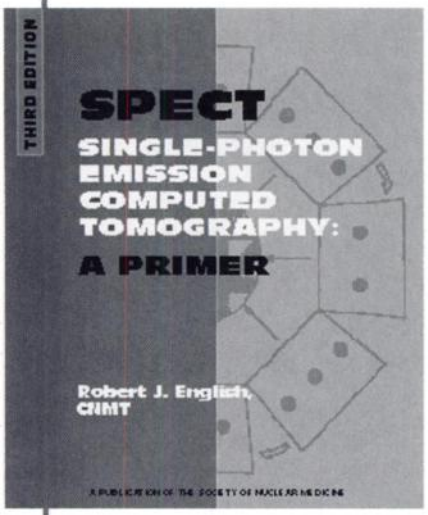

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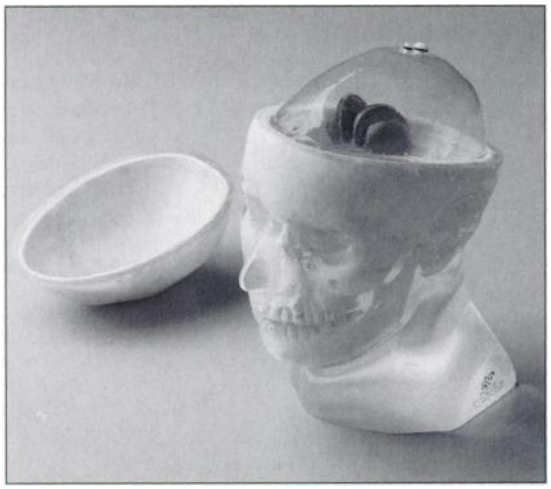

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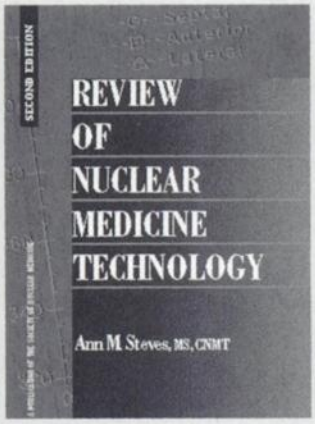

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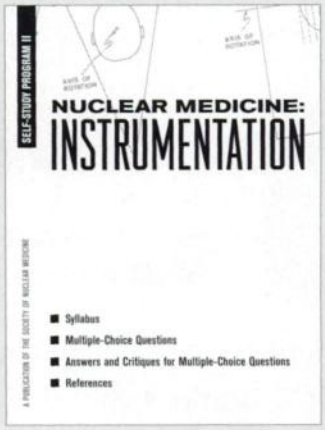

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A one or two year fellowship position in brain imaging is available beginning July 1, 1997 in the Division of Nuclear Medicine, Department of Radiology, at the University of Alabama Medical Center at Birmingham. Applicants should have completed a residency in nuclear medicine or radiology, have an intense interest in both clinical and research brain imaging and should be eligible for licensure in the state of Alabama. Successful candidates will assume a significant role in multiple research projects involving all aspects of clinical brain SPECT imaging, triple head dynamic brain SPECT, quantitative Xe-133 brain SPECT on the Picker Prism, and 4.1T NMR metabolic and fMR brain imaging. Please send letter of interest and curriculum vitae to: James M. Mountz, MD, PhD, Director of Neuro-Nuclear Imaging, Division of Nuclear Medicine, Department of Radiology, The University of Alabama at Birmingham, 619 South 19th Street, Birmingham, AL 35233-6835. Phone: 205-975-8336, Fax: 205-934-5589. E-mail: medy010@uabdpo.dpo.uab.edu (UAB is an Affirmative Action/Equal Opportunity Employer).

Postdoctoral Fellowship in PET/SPECT/fMRI Imaging

Unique opportunity for postdoctoral training in functional imaging research. Emphasis on neuropsychiatric, psychopharmacologic, oncology imaging and qualification techniques. Excellent mix of clinical and basic research. Opportunity for fMRI/PET correlation. MD and clinical credentials required. May start as early as May/June 1997. Applications to: Dean F. Wong, MD, PhD, Johns Hopkins Medical Institute, Radiology-JHOC Bldg., Room 3245, 601 N. Caroline Street, Baltimore, MD 21287-0807. E-mail: dfwong@rad.jhu.edu.

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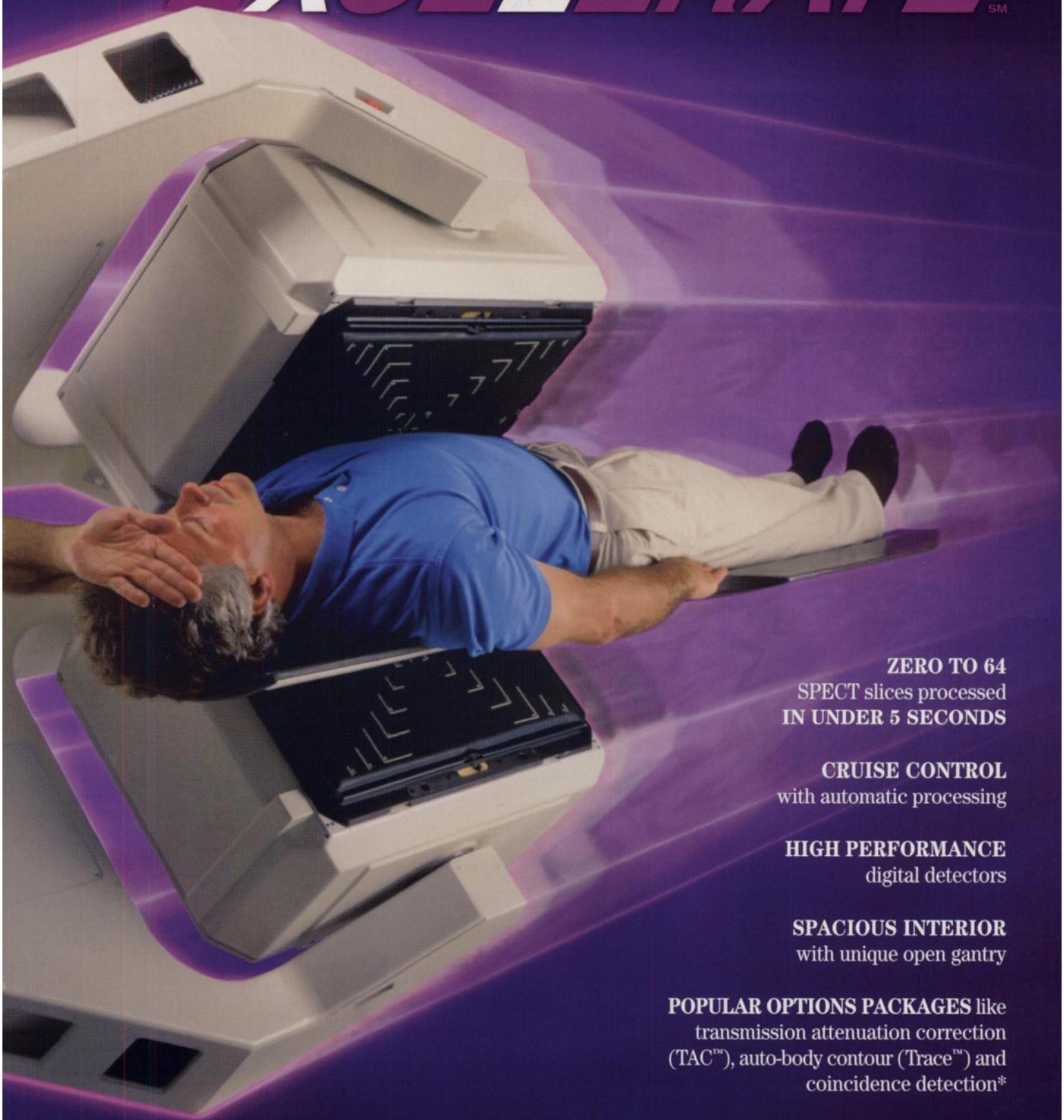

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