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**THE JOURNAL OF NUCLEAR MEDICINE** (ISSN 0161-5505) is published monthly by the Society of Nuclear Medicine Inc., 1850 Samuel Morse Drive, Reston, VA 20190. Periodicals Postage Paid at New York, NY and additional mailing offices. *Postmaster*, send address changes to *The Journal of Nuclear Medicine*, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

**EDITORIAL COMMUNICATIONS** should be sent to the Editor: Stanley J. Goldsmith, MD, *The Journal of Nuclear Medicine*, 402 E. 64th St., Suite 1A, New York, NY 10021; (212) 906-9060, Fax: (212) 906-9056. *Books and monographs* covering the use of nuclear medicine and its allied disciplines will be reviewed as space is available. *Send review copies to the Editor.*

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**SUBSCRIPTION RATES** for 1996 calendar year (effective Sept. 1, 1995) are \$140 within the United States; \$155 for Canada and Pan American countries; \$185 elsewhere. Student subscriptions are \$80 (with proof of student status). Single copies \$15.00; foreign \$18.00; convention issue (May) \$18.00; foreign \$20.00. Make checks payable to the Society of Nuclear Medicine. Sales of individual back copies of 1992 through the current issue of *JNM* are available through Matthews Medical Books, 11559 Rock Island Court, Maryland Heights, MO 63043, (800)633-2665 or (314) 432-1401. *JNM* is also available in machine-readable format from University Microfilms Intl., 300 N. Zeeb Rd., Ann Arbor, MI 48106, (800) 521-0600.

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## Gray Hair

**W**hen was the first time you saw a gray hair? Not just any gray hair; your gray hair, your first gray hair?

It seems that people can be categorized as one of two types: those for whom a gray hair is just a gray hair, perhaps part of a process, a milestone along the journey of life.

For others, it is an ominous sign: a sign that something bad has happened, a source of unhappiness. These individuals may pull out the offending gray hair so as to deny its existence and the reminder of the biology of aging: that tell-tale sign that we are not as young as we used to be. It's as though, if we do not see it, it does not exist; the personal and visual equivalent of the existential question "If a tree falls in the forest and no one hears it...?"

We all value many things "that get better with age": cheese, wine, coins, stamps, art and furniture. Why is that some people are troubled by their own aging? Why are we not able to think of ourselves in the same way we think of a good Bordeaux or camembert: We are getting better and more distinctive with unique and special qualities as we age?

Certainly there are benefits related to the aging process—even before Medicare or Golden Age discounts on airplanes and at the movies kick in.

When "things" do not go as I had wished, I am not as bitterly disappointed. After all, I know from experience that "these things happen." When events do not progress as fast as I would have liked, I am less discontent. These "things" have happened before; it is not surprising that they are happening again.

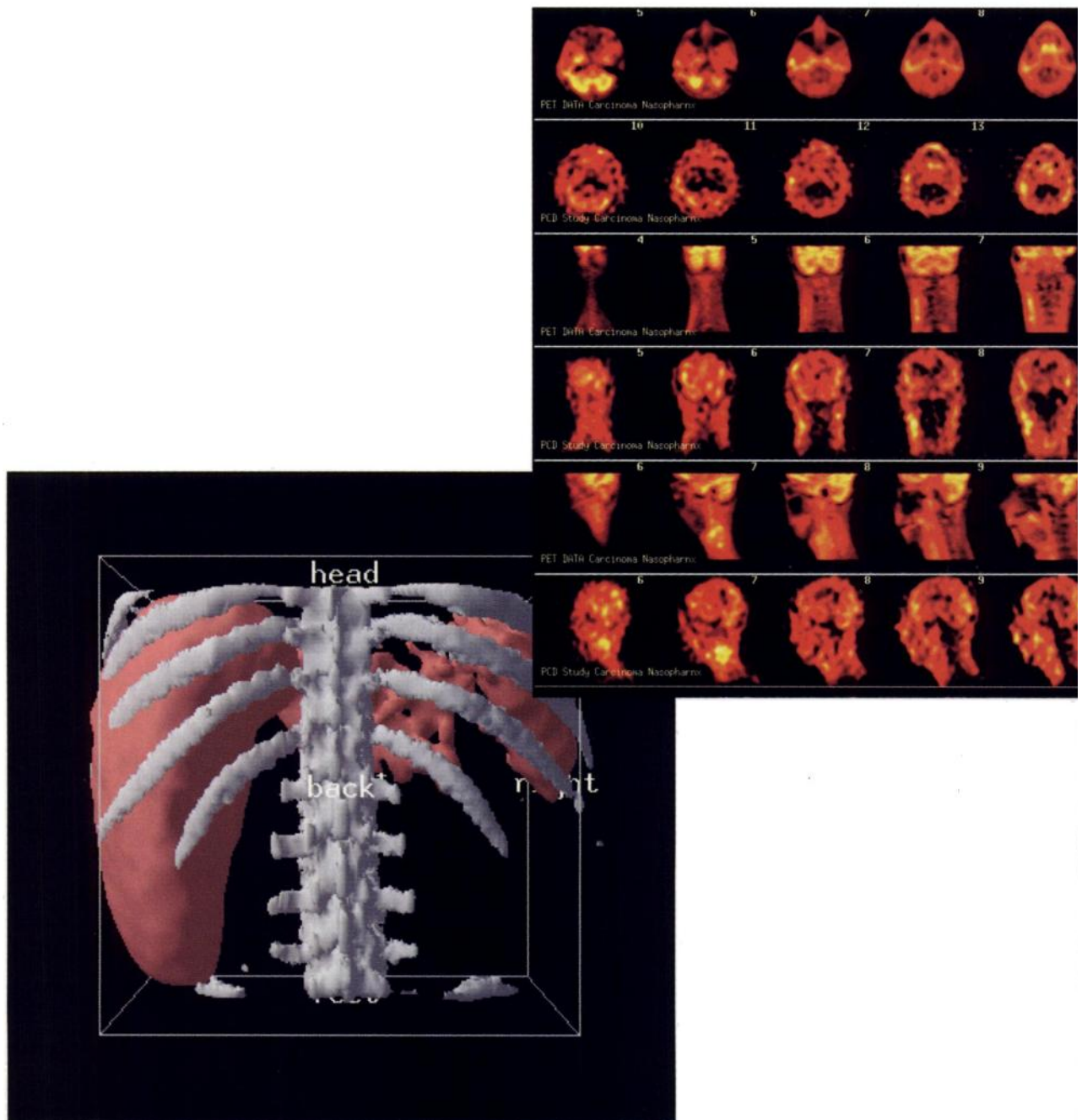
Yes indeed, there is nothing like experience. Stay calm. None of these things are really unexpected any longer. "It" is all just part of life. Maybe even enriching, an experience I will look back on and savor.

Wait a minute! Is that another gray hair?

**Stanley J. Goldsmith, MD**  
*Editor-in-Chief, The Journal of Nuclear Medicine*  
November 1996



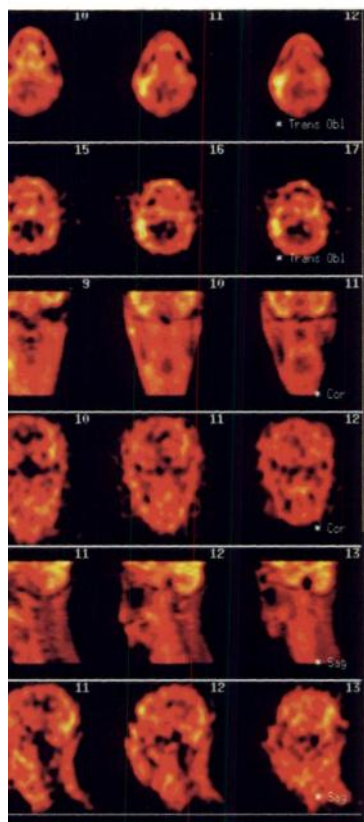
# A Look Into The Future...



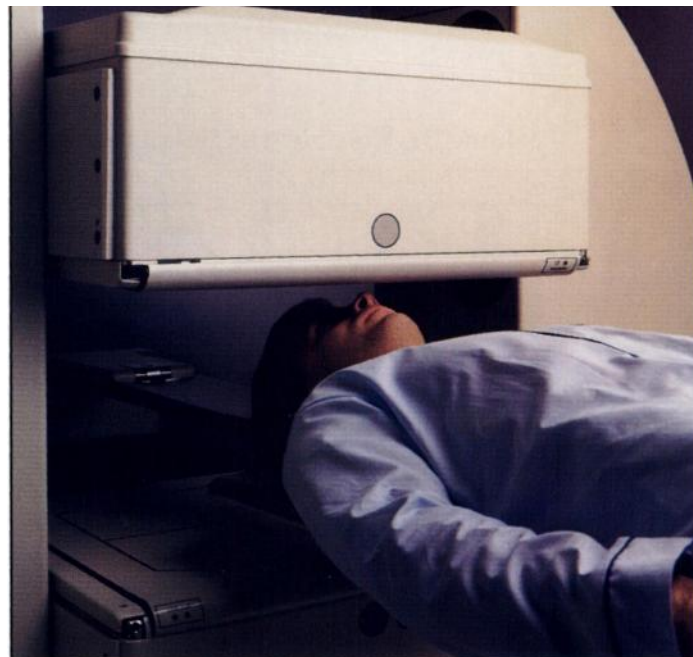
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## Positron Coincidence Detection

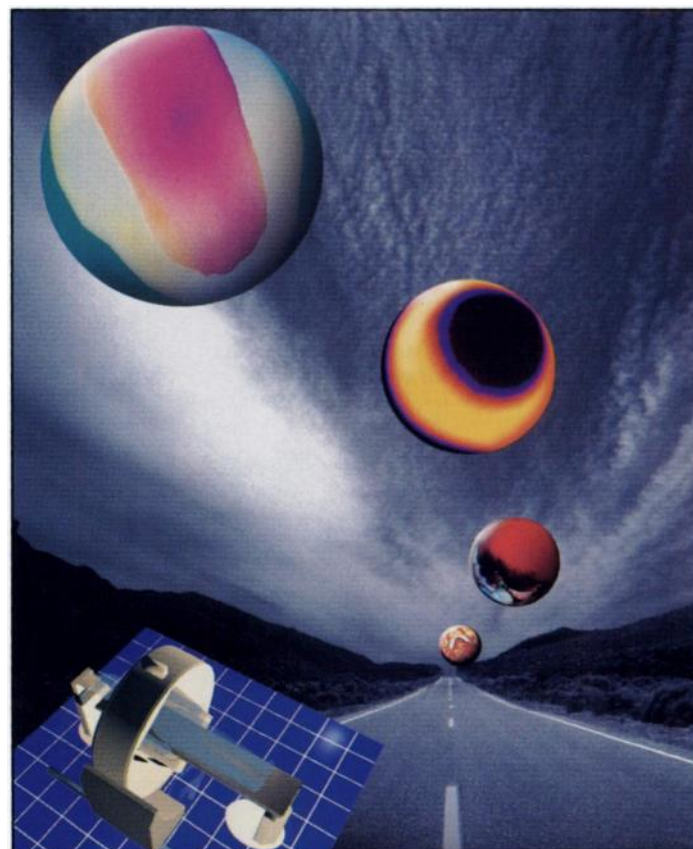
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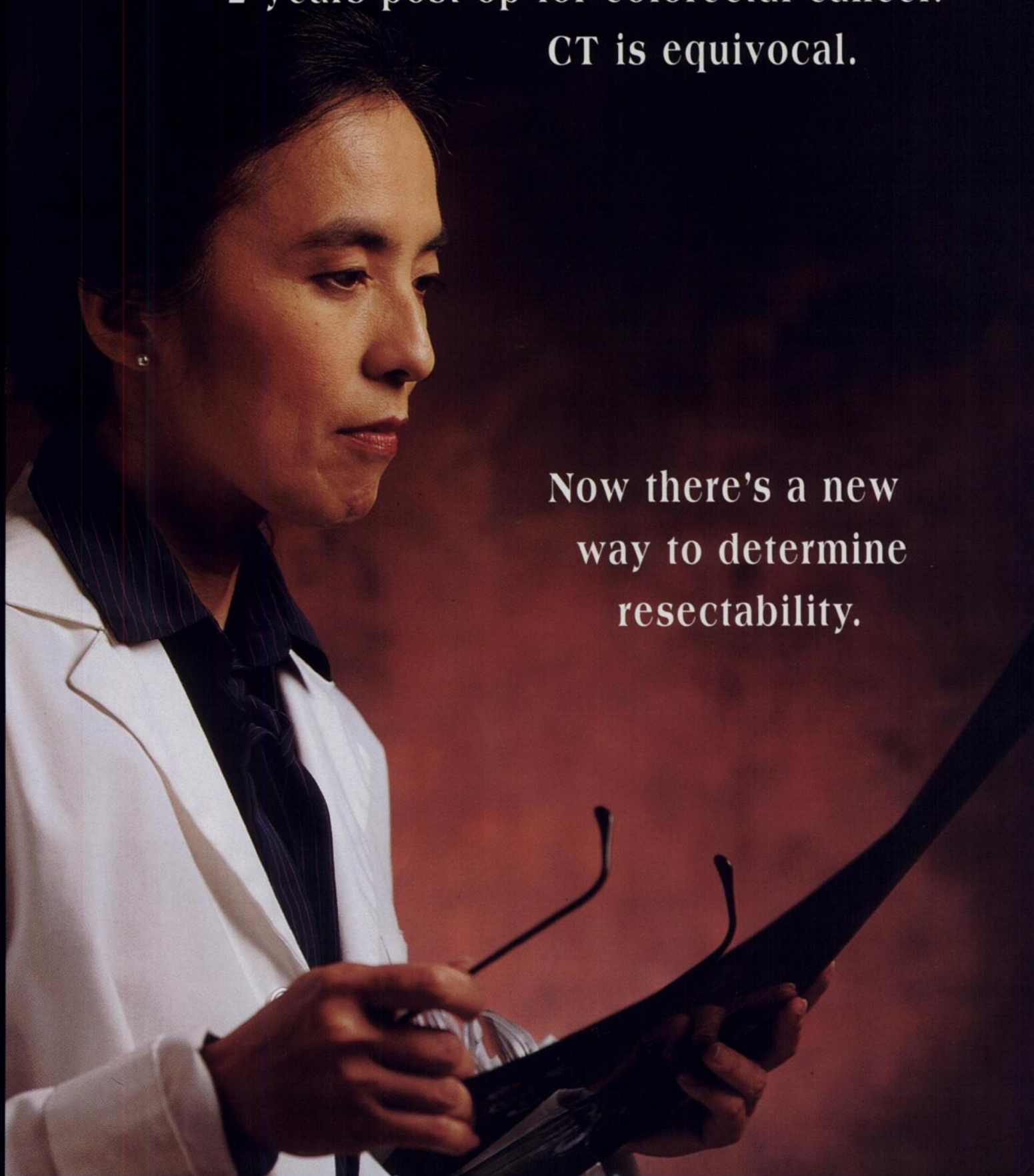
Asymptomatic.

Rising CEA.

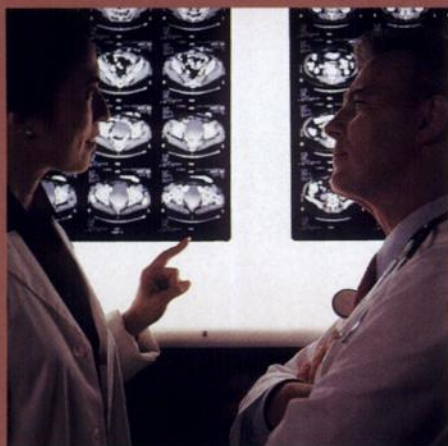
2 years post-op for colorectal cancer.

CT is equivocal.

Now there's a new  
way to determine  
resectability.







I N T R O D U C I N G

# CEA-SCAN<sup>®</sup> (Arcitumomab)

## SENSITIVE IMAGING TO HELP DRIVE MANAGEMENT DECISIONS

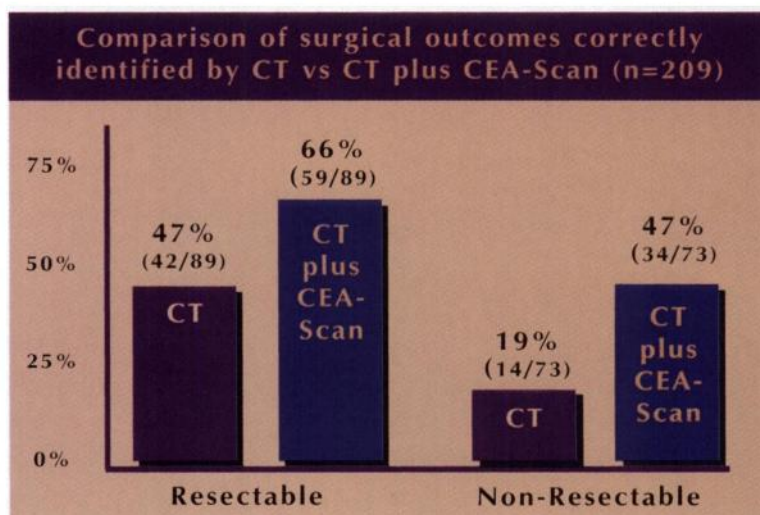
**C**EA-Scan is a new imaging agent that enhances your pre-operative determination of colorectal cancer resectability. CEA-Scan is indicated, in conjunction with standard diagnostic evaluations, for detection of the presence, location and extent of recurrent and/or metastatic colorectal carcinoma involving the liver, extra-hepatic abdomen and pelvis in patients with a histologically confirmed diagnosis of colorectal carcinoma.

Surgery confirms that CEA-Scan with CT can help you make decisions concerning surgical resectability. Compared to CT alone, CEA-Scan with CT:

- Identified 59/89 versus 42/89 patients with resectable disease, a 40% increase in detection rate
- Identified 34/73 versus 14/73 patients with non-resectable disease, or more than twice as many
- In patients with negative or equivocal CT (occult disease), reduced the number of false-negative patients from 59 to 23, a 60% decrease.<sup>1</sup>

CEA-Scan has a 97% positive predictive value for lesions when concordant with CT (146 true-positive lesions versus 4 false-positives).

### BETTER IDENTIFICATION OF RESECTABLE/NON-RESECTABLE DISEASE



### IMPROVES SENSITIVITY

#### Sensitivity and specificity of CEA-Scan vs standard diagnostic methods (SDM)<sup>1</sup>

	SDM		CEA-Scan
Sensitivity	57.9% (103/178)	P=0.006	71.3% (127/178)
Specificity	84.4% (27/32)	P=0.12	62.5% (20/32)

## SENSITIVE, SAME-DAY IMAGING

CEA-Scan enables improved colorectal cancer detection compared to standard diagnostic methods (SDM, 95% of which were CT).

- In general, CEA-Scan was more sensitive and less specific in the abdomen and pelvis than CT<sup>1</sup>
- However, direct comparisons of the performance characteristics of SDM to CEA-Scan are difficult to interpret, since the results of SDM were entry criteria for both Phase 3 protocols.

## ADVANCED TECHNOLOGY

CEA-Scan offers the advantages of Fab' fragment design.

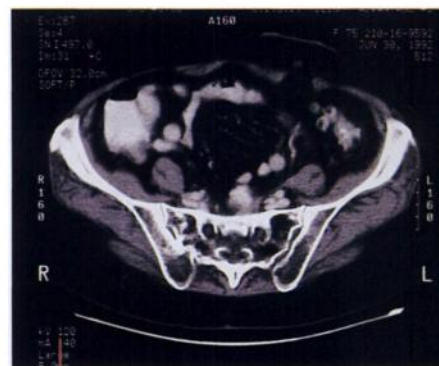
- Short biological half-life ( $13 \pm 4$  hours) and rapid blood clearance improve tumor-to-background ratios<sup>2</sup>
- Minimal liver metabolism allows hepatic imaging
- Small fragment size enhances renal clearance
- Fragment technology provides lower immunogenicity

## ESTABLISHED SAFETY PROFILE

Over 400 patients who have received CEA-Scan have been evaluated for human anti-mouse antibody (HAMA).

- <1% showed an elevation of HAMA levels
- Limited data are available regarding the safety of re-administration

In the patients studied with CEA-Scan, one patient each developed the following minor self-limiting adverse effects: transient eosinophilia, nausea, bursitis, urticaria, generalized itching, headache, upset stomach and fever. Out of a total of over 500 patients receiving the product to date, there has been a single report of an apparent grand mal epileptic seizure in a severely hypertensive patient that was "possibly related" to CEA-Scan infusion.



Patient underwent abdominoperineal resection in 1987. Presented 5 years post-op with negative CT and rising CEA.



CEA-Scan abdominal SPECT image indicating tumor uptake (T, arrow). Surgery confirmed the positive CEA-Scan image.

## HELPING YOU MAKE DECISIONS ABOUT TUMOR RESECTABILITY

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### References:

1. Moffat FL Jr., Pinsky CM, Hamershaime L, et al. Clinical utility of external immunoscintigraphy with the IMMU-4 technetium-99m-Fab' antibody fragment in patients undergoing surgery for carcinoma of the colon and rectum. Results of a pivotal, Phase III trial. *J Clin Oncol.* 1996;14:2295-2305.
2. Tempero M, Brand R, Holdeman K, Matamoros A. New imaging techniques in colorectal cancer. *Semin Oncol.* 1995; 22(5):448-471.



# CEA-SCAN® (Arcitumomab)

For the Preparation of Technetium Tc 99m Arcitumomab.  
Sterile, Non-Pyrogenic, Lyophilized Powder for Intravenous Use Only.

## DESCRIPTION

CEA-Scan® is a radiodiagnostic agent consisting of a murine monoclonal antibody Fab' fragment, arcitumomab, formulated to be labeled with <sup>99m</sup>Tc. The active component, arcitumomab, is a Fab' fragment generated from IMM-4, a murine IgG<sub>1</sub> monoclonal antibody produced in murine ascitic fluid supplied to Immunomedics, Inc., by Charles River Laboratories. IMM-4 is purified from the ascitic fluid and is digested with pepsin to produce F(ab')<sub>2</sub> fragments and subsequently reduced to produce the 50,000-dalton arcitumomab. Each vial contains the non-radioactive materials necessary to prepare one patient dose. CEA-Scan® is a sterile, lyophilized formulation, containing 1.25 mg of arcitumomab and 0.29 mg stannous chloride per vial, with potassium sodium tartrate tetrahydrate, sodium acetate trihydrate, sodium chloride, acetic acid, glacial, hydrochloric acid, and sucrose. The imaging agent, technetium Tc 99m CEA-Scan®, technetium Tc 99m arcitumomab, is formed by reconstitution of the contents of the CEA-Scan® vial with 30 mCi of [<sup>99m</sup>Tc] sodium pertechnetate in 1 ml of Sodium Chloride for Injection, USP. The resulting solution is pH 5-7 and for intravenous use only. Following administration, the labeled antibody can be visualized by common nuclear medicine instrumentation.

## INDICATIONS

CEA-Scan® (Arcitumomab) is indicated, in conjunction with standard diagnostic evaluations (e.g., additional imaging evaluation), for detection of the presence, location and extent of recurrent and/or metastatic colorectal carcinoma involving the liver, extrahepatic abdomen and pelvis in patients with a histologically confirmed diagnosis of colorectal carcinoma. CEA-Scan® provides additional information in patients with no evidence of disease by standard diagnostic modalities (SDM) in whom recurrence or metastasis is suspected based upon elevated or rising serum CEA, and in patients with evidence of metastatic or recurrent disease on SDM. A retrospective analysis suggests that these data can be useful in the evaluation of patients in whom surgical intervention (biopsy, exploratory laparotomy and surgical resection) is under consideration.

CEA-Scan® is not indicated for the differential diagnosis of suspected colorectal carcinoma or as a screening tool for colorectal cancer. CEA-Scan® is not intended for readministration or for assessment of response to treatment. (see PRECAUTIONS)

## CONTRAINDICATIONS

CEA-Scan® should not be administered to patients who are hypersensitive to products of murine origin or to Technetium [Tc-99m].

## WARNINGS

Anaphylactic and other hypersensitivity reactions can occur following administration of mouse protein to patients. Although serious reactions of this type have not been observed in clinical trials after CEA-Scan® administration, medications for the treatment of hypersensitivity reactions, e.g., epinephrine, antihistamines and corticosteroids, should be available for immediate use in the event of an allergic reaction during administration of this agent.

## PRECAUTIONS

### General

CEA-Scan® is to be interpreted in conjunction with standard diagnostic modalities. A negative or positive CEA-Scan® by itself should not be utilized in the diagnostic evaluation of colorectal cancer. Discordant results are substantially less predictive than concordant results.

CEA-Scan® should not be used as a screening test for colorectal cancer.

Limited data are available regarding the safety of readministration.<sup>2</sup> There are no data to support the efficacy of CEA-Scan® readministration. CEA-Scan® should be used only once in each patient.

The components of CEA-Scan® are sterile and non-pyrogenic. It is essential to follow preparation directions carefully and to adhere to strict aseptic procedures during preparation of CEA-Scan® [<sup>99m</sup>Tc]. The contents of the vial are intended only for use in the preparation of CEA-Scan® [<sup>99m</sup>Tc] and are not to be administered directly to patients.

The contents of the vial before preparation are not radioactive. However, after <sup>99m</sup>Tc-pertechnetate is added, adequate shielding of the preparation must be maintained. Appropriate safety measures should be used to minimize radiation exposure to clinical personnel and patients, consistent with proper patient management.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides.

### Imaging Interpretation

#### General

There are limited data to determine the imaging characteristics and efficacy of the CEA-Scan® (Arcitumomab) in detection of lesions outside of the abdominopelvic cavity.<sup>2,3</sup>

Areas of potential false-positive readings, particularly with planar imaging, may be observed near the major bloodpool organs (heart, major vessels, etc.) at very early imaging times, near the sites of antibody fragment metabolism (kidneys and urinary bladder), and in the intestines and gallbladder. Late imaging may also aid in the evaluation of suspected normal bowel activity.

With regard to imaging of tumor near the kidneys or urinary bladder, it is advisable to have the patient void urine prior to acquisition of imaging data to decrease bladder activity. Careful SPECT imaging near the kidneys and bladder has been helpful.

### Porta Hepatis Region

Precise localization of lesions in the region of the porta hepatis has been difficult. Lesions within the porta hepatis region may be present within the liver or the portal nodes. At the time of surgical exploration, such lesions (which if nodal would preclude resection of hepatic metastases) should be explored first.

### False-Positive Lesions

There were 52 false-positive lesions observed in 41 patients from a total of 209 surgically explored subjects in the two pivotal trials. Thirty-five of these lesions were in occult disease patients. Of the 52 false-positive lesions, 11 were observed in the liver, 17 in the extra-hepatic abdomen, and 24 in the pelvis. A pathological correlate to the lesions was infrequently documented; these included granulomas in the liver (1 instance), adhesions with or without suture granulomas (4 cases), surgical incision site (1 case). Descriptions of false-positive lesions within the abdomen were suggestive of colonic activity in several cases.

### Hot, Rimmed, and Cold Lesions

Only hot or rimmed lesions should be considered as positive for tumor. Lesions that are rimmed or cold usually fill in as hot or rimmed, respectively, with time.<sup>3,4</sup> Often, large lesions, due to poor vascularization or central necrosis, will appear to be cold.

### Information for Patients

Murine monoclonal antibodies are foreign proteins, and their administration can induce human anti-mouse antibodies (HAMA). While limited data exist concerning the clinical significance of HAMA, the presence of HAMA may interfere with murine antibody-based immunoassays (e.g., serum CEA assays), could compromise the efficacy of *in vitro* or *in vivo* 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 CEA-Scan®, and they should be advised to discuss prior use of murine-based antibody products with their physicians. (see Heterologous Protein Administration)

### Heterologous Protein Administration

The presence of HAMA and human anti-mouse fragment antibodies have been reported in patients before and after receiving CEA-Scan® (<1% of patients develop HAMA to the antibody fragment). While hypersensitivity reactions to CEA-Scan® have not been observed to date, it is possible that such reactions could occur, resulting in anaphylactic shock, serum sickness or death. In addition, patients who have previously received murine monoclonal antibody products are more likely to have HAMA. When considering the use of the CEA-Scan® in patients who have previously received murine antibody-based products, physicians should be aware of the potential for HAMA to increase the risk of allergic reactions and to alter clearance and biodistribution. The quality or sensitivity of the imaging study may then be compromised.

### Drug/Laboratory Test Interactions

The presence of HAMA in serum may interfere with two-site murine antibody-based immunoassays, such as assays for CEA and CEA-125. If HAMA is known or suspected to be present, the clinical laboratory should be notified that interference may occur.

CEA-Scan® may interfere with serum assays for assessment of serum levels of CEA. Therefore, any determination of serum CEA should be made prior to injection with CEA-Scan®. Assays for serum CEA should not be performed within 7 days after injection of CEA-Scan®.

No data are available on possible drug interactions. Do not mix or administer CEA-Scan® with other products. Sufficient time should be allowed for clearance and radioactive decay before and after the use of this product and other products using radionuclides.

### Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate the carcinogenic or mutagenic potential of Technetium Tc 99m arcitumomab or to determine its effects on fertility in males or females.

### Pregnancy - Category C

Animal reproduction studies have not been conducted with CEA-Scan®. It is also not known whether it can cause fetal harm or affect reproductive capacity when administered to a pregnant woman. CEA-Scan® should be used during pregnancy only if, in the opinion of the physician, the information to be gained justifies the potential risk to the fetus. Examinations using a radiopharmaceutical in a woman of child-bearing capability should be performed during the first 8-10 days following the onset of menses, if possible.

### Lactation

Before administering a radioactive medicinal product to a mother who is breast feeding, consideration should be given whether the investigation could be reasonably delayed until the mother has ceased breast feeding. If the use of the product is deemed to be clinically indicated, breast feeding should be interrupted, the expressed milk discarded, and formula feedings substituted for breast feeding.

### Pediatric Use

Safety and diagnostic accuracy in persons under 21 years of age have not been established.

### ADVERSE REACTIONS

In the patients studied with CEA-Scan®, one patient each developed the following minor self-limiting adverse effects: transient eosinophilia, nausea, bursitis, urticaria, generalized itching, headache, upset stomach and fever. Out of a total of over 500 patients receiving the product to date, there has been a single report of an apparent grand mal epileptic seizure in a severely hypertensive patient that was "possibly related" to CEA-Scan® infusion.

Over 400 patients who have received CEA-Scan® have been evaluated for HAMA by Immunomedics using ELISA methodology. Fewer than 1% of the patients showed an elevation of HAMA levels to fragment after being injected with CEA-Scan®. If the physician suspects HAMA based on an adverse reaction or altered biodistribution pattern, and deems that a HAMA assay is clinically warranted, he/she should telephone Immunomedics, Inc., at 800 327-7211, between 8:30 a.m. and 5:00 p.m. Eastern Standard Time, for information on procedures to be followed for submission of patient serum for assessment of HAMA directed against mouse monoclonal antibody fragments.

### OVERDOSAGE

Intravenous infusion of intact IgG and F(ab')<sub>2</sub> of IMM-4 in doses of up to 25 mg or arcitumomab at doses up to 10 mg have not shown any serious adverse reaction.

### HOW SUPPLIED

Package containing one (1) vial, with a single-use dose of 1.25 mg lyophilized arcitumomab. The product should not be used beyond the expiration date printed on the label.

### REFERENCES


1. Hansen HJ, Jones AL, Sharkey RM, Grebenau R, Blazejewski N, Kunz A, Buckley MJ, Newman ES, Ostella F, Goldenberg DM. Preclinical evaluation of an "instant" <sup>99m</sup>Tc-labeling kit for antibody imaging. *Cancer Res.* 1990;50:794-798.
2. Data on File at Immunomedics, Inc.
3. Moffat FL, Pinsky CM, Hammershaimb L, Petrelli NJ, Patt YZ, Whaley FS, Goldenberg DM, and the Immunomedics Study Group. Clinical utility of external immunoscintigraphy with the IMM-4 technetium-99m-Fab' antibody fragment in patients undergoing surgery for carcinoma of the colon and rectum. Results of a pivotal, Phase III trial. *J Clin Oncol* 1996;14:2295-2305.
4. Behr T, Becker W, Hanappel E, Goldenberg DM, Wolf F. Targeting of liver metastases of colorectal cancer with IgG, F(ab')<sub>2</sub>, and Fab' anti-carcinoembryonic antigen antibodies labeled with <sup>99m</sup>Tc: the role of metabolism and kinetics. *Cancer Res.* 1995;55:5777s-5785s.

Immunomedics, Inc.  
300 American Road  
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**CEA-SCAN<sup>®</sup>**  
(Arcitumomab)

## Antibody Fragment Imaging: A Step Toward Nuclear Medicine's Future

110A0071

Nuclear medicine's future depends upon its ability to better detect and treat disease. So you have a stake in the future of CEA-Scan<sup>®</sup> (Arcitumomab), a new radiodiagnostic agent for detection and staging of recurrent and metastatic colorectal cancer.

CEA-Scan is the first Tc99m-labeled antibody. The first antibody fragment. The first same-day antibody fragment imaging agent. The first antibody fragment diagnostic agent with the ability to detect liver metastases. And the first with virtually no immunogenicity (less than 1%).

With CEA-Scan and CT, you can help oncologists and surgeons better evaluate the 600,000 Americans who've undergone laparotomy for colorectal cancer. You can better detect lesions which, if excised, make surgical cure possible. Conversely, CEA-Scan and CT can detect otherwise occult disease that can make such resection useless.

Soon, we'll be introducing additional products for the diagnosis and treatment of other diseases, providing truly new capabilities for nuclear medicine, and those who practice it.

 **IMMUNOMEDICS, INC.**

300 American Road, Morris Plains NJ 07950  
Phone: 201-605-8200 Fax: 201-605-8282

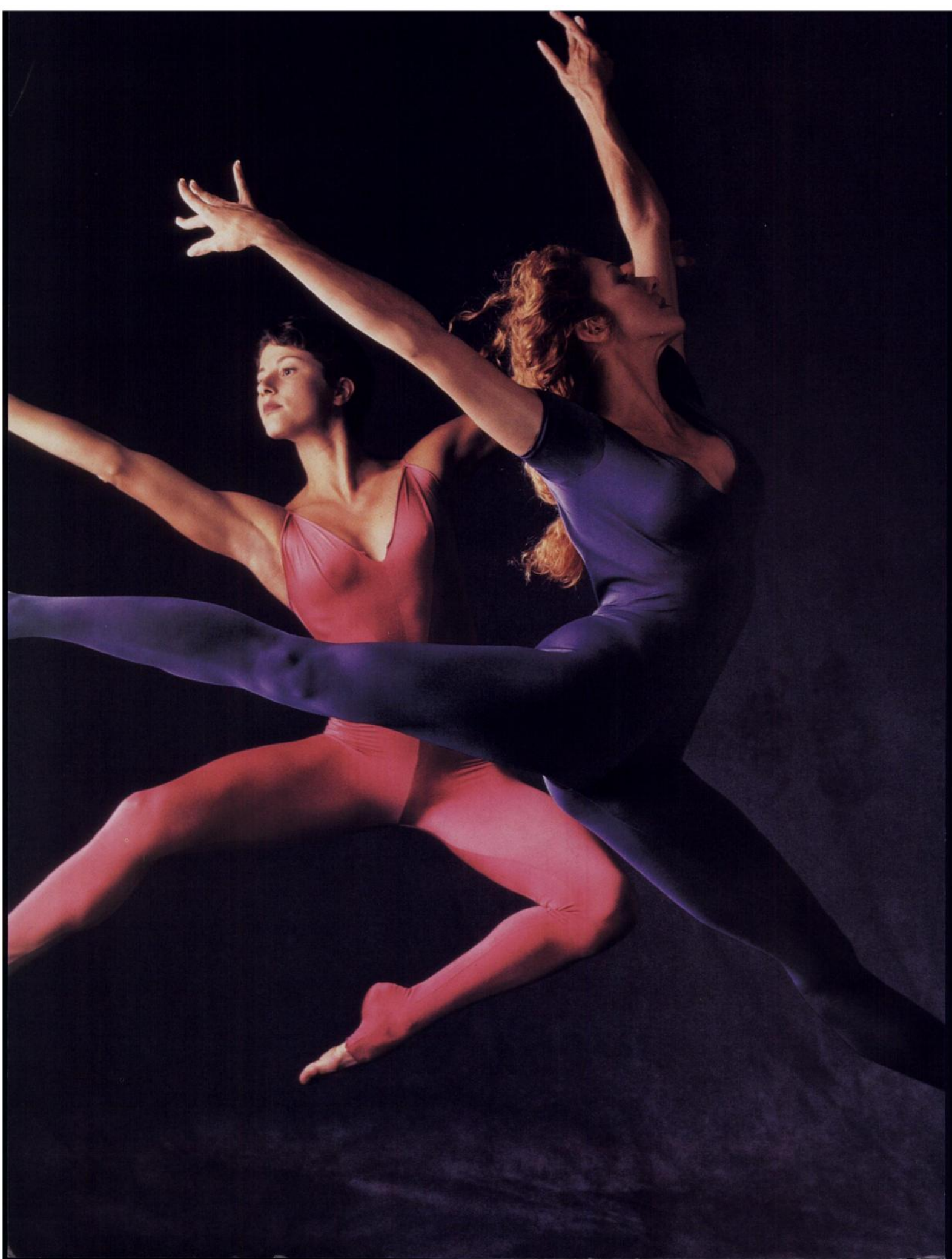
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Please see preceding page for a brief summary of prescribing information.

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# *Confidence in motion*

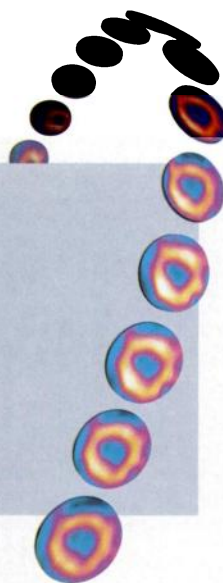
The goal of cardiac imaging is to obtain studies that allow you to accurately view the status of cardiac perfusion and function. And that's where Cardiolite® comes through.

With *gated stress Cardiolite studies*, you simultaneously obtain stress perfusion and resting function (wall motion, wall thickening, and LVEF)—that's more diagnostic information than perfusion alone, which can help you improve patient management. And, the higher photon energy (140 keV) reduces attenuation and improves image quality.

So remember, to enhance interpretive confidence and patient management, perform gated stress Cardiolite.

With gated stress Cardiolite studies you can...

- Acquire stress perfusion and resting function from one study
- Obtain function information for patients with diseases that coexist with CAD (eg, cardiomyopathies)
- Differentiate scar tissue from artifact
- Potentially reduce false-positive interpretations and the need for other costly and invasive procedures



## Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

***To reduce the uncertainty  
Cardiolite comes through***



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.*

© 1996, DuPont Pharma



## 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 (1.5 rads/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,  $[\text{Cu}(\text{MIBD})_4]\text{BF}_4$ , 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 ( $\geq 20\mu\text{g/ml}$ ), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay.  $[\text{Cu}(\text{MIBD})_4]\text{BF}_4$  did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/kg,  $> 600 \times$  maximal human dose).

#### Pregnancy Category C

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

#### Nursing Mothers

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

#### Pediatric Use

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

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**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, dyspnea, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, and hypotension also have been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (see WARNINGS and PRECAUTIONS). The following adverse reactions have been rarely reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis in a wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthenia and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

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

370-1110MBq (10-30mCi)

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

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

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Radiochemical purity should be checked prior to patient administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

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

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

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

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

Organ	STRESS			
	2.0 hour void		4.8 hour void	
	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.8
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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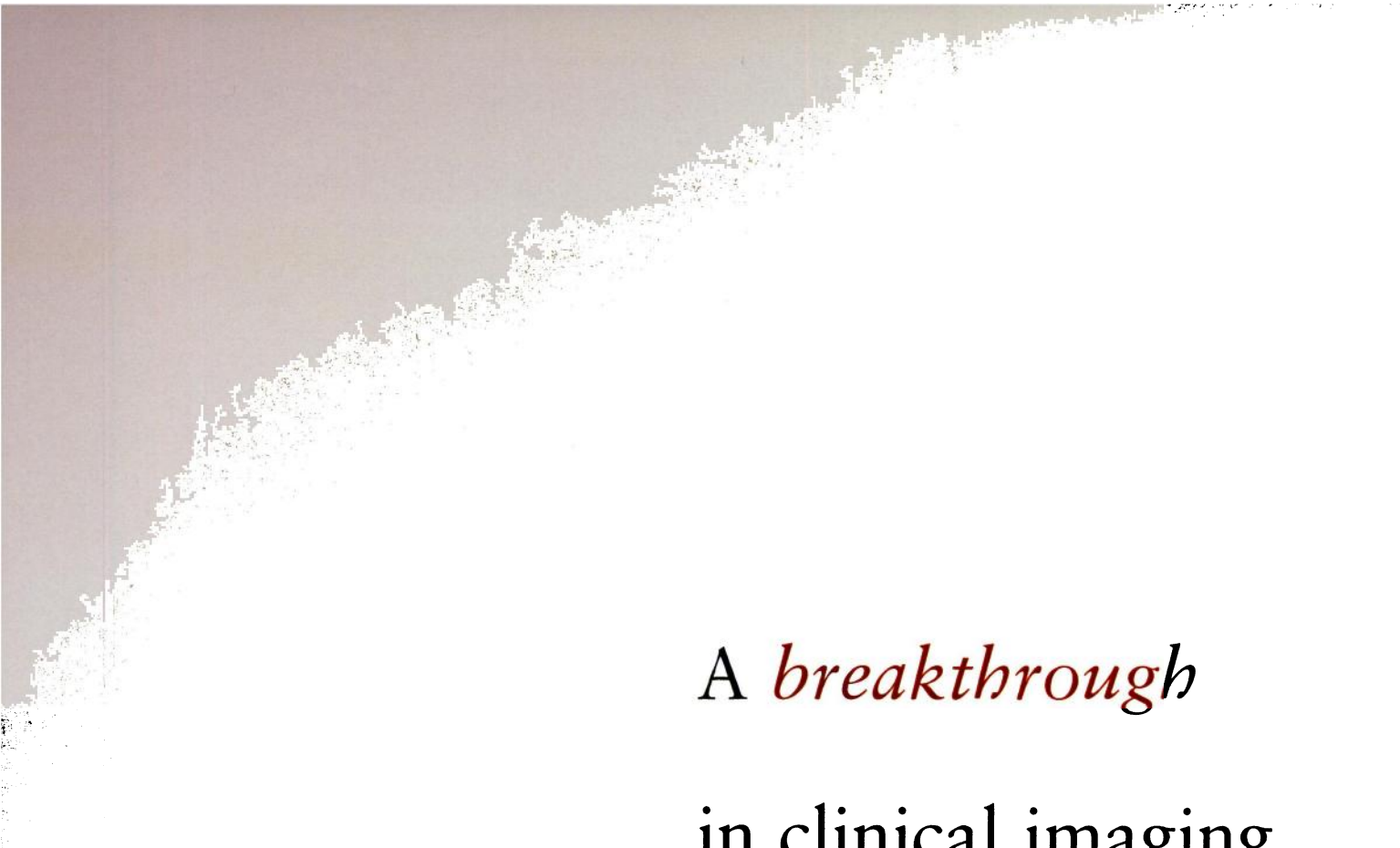
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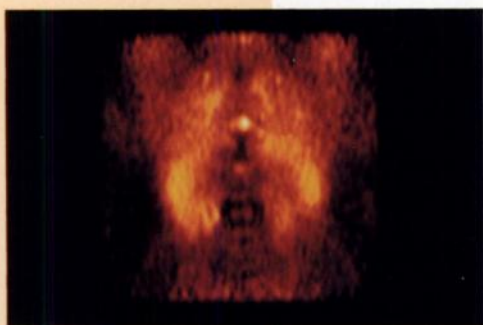
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# 1

**CORONAL VIEW OF PATIENT**

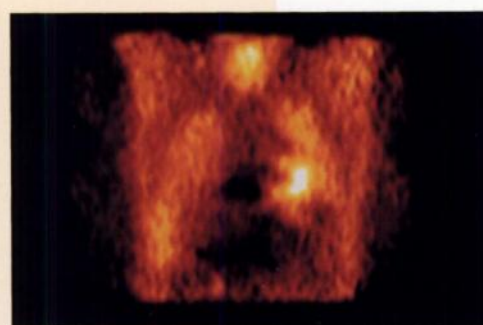
*with lung cancer. MCD scan revealed abnormal uptake of FDG, showing primary tumor and metastatic disease.*



# 2

**TRANSVERSE VIEW OF PATIENT**

*with epilepsy. MCD scan revealed decreased activity of FDG in right lobe.*



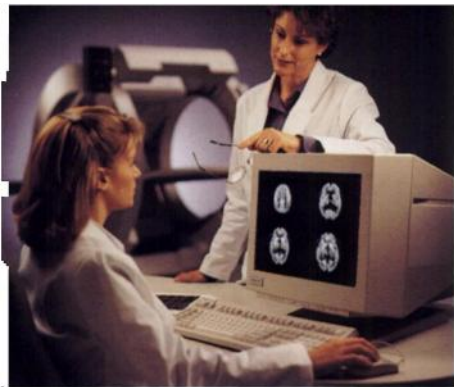
# 4

**CORONAL VIEW OF PATIENT**

*with esophageal cancer. MCD scan revealed abnormal uptake of FDG in the neck correlating with PET and CT scans.*

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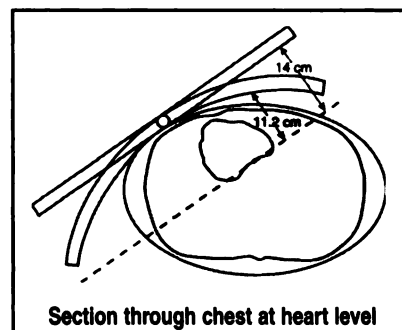
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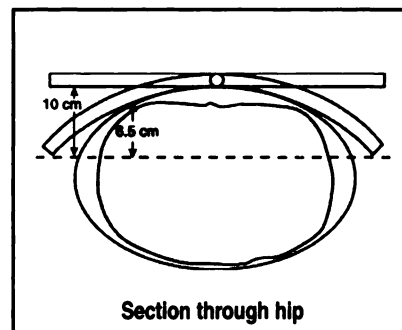
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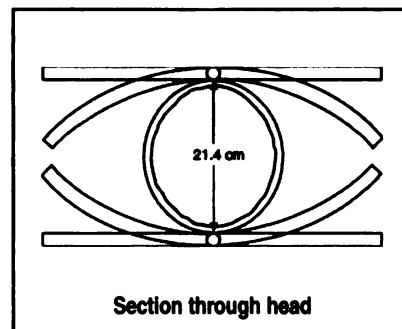
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Section through head

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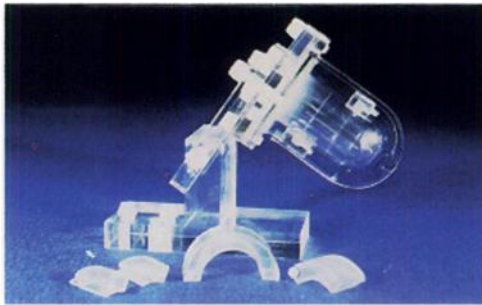
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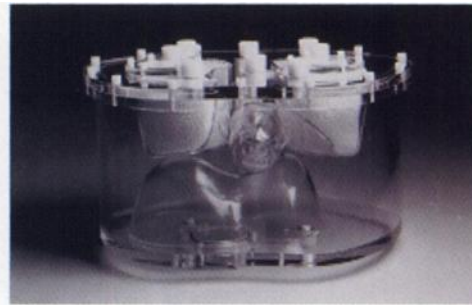
## ECT Cardiac Insert Phantom with Fillable Defect Set (Model ECT/CAR/I)



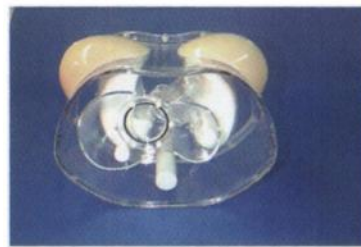
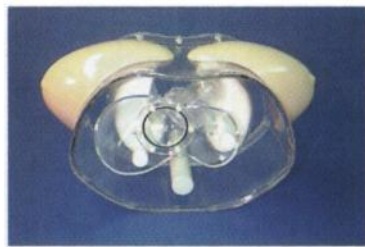
**Example SPECT horizontal long-axis (left), vertical (center) and short axis (right) images of Cardiac Insert with 50% cold defect. Filtered backprojection images acquired with Cardiac Insert mounted in Anthropomorphic Torso Phantom (optionally available) as pictured below.**



**Cardiac Insert shown separately with Fillable Defect Set. Insert may also be used in Cylindrical and Elliptical Phantoms.**



**Cardiac Insert shown mounted in Anthropomorphic Torso Phantom Model ECT/TOR/P.**



**To study the effect of breast attenuation on cardiac images, Breast Attachments large (left) or medium (right) may be used together with the Torso Phantom and Cardiac Insert.**

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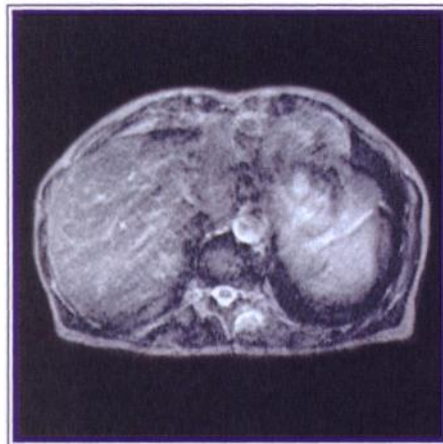
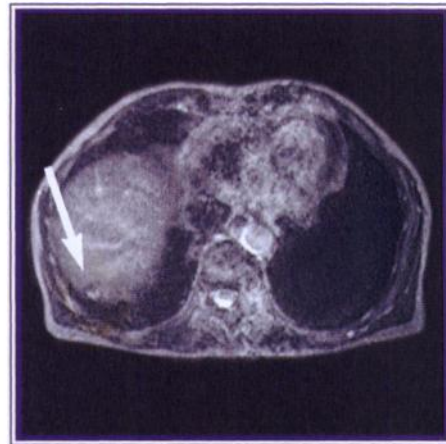


Neuroendocrine Tumor Case Review

# 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**

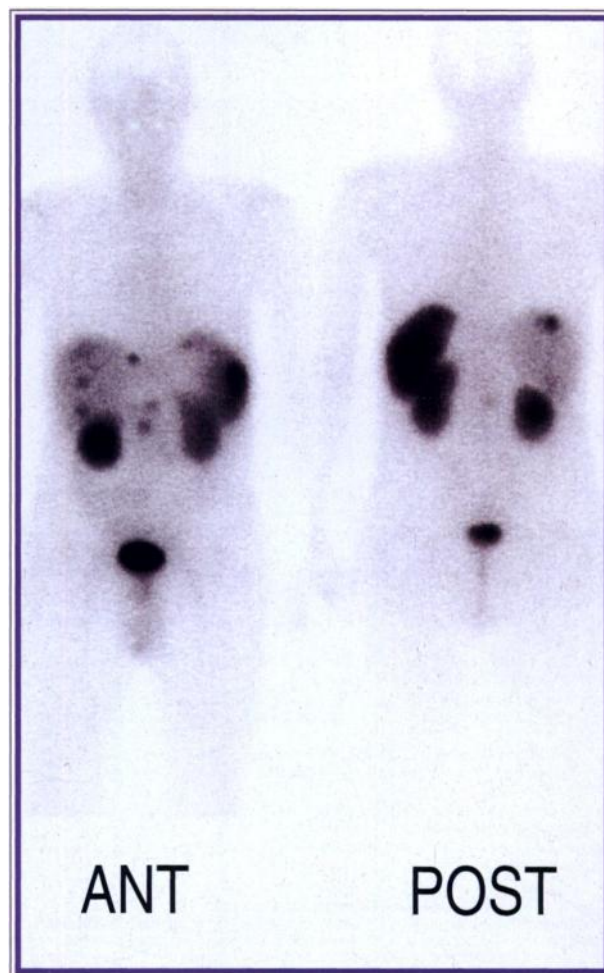
Five hepatic tumors and two periaortic nodal lesions were clearly visible on the whole-body planar images. OctreoScan imaging enabled differentiation between a non-receptor-expressing cavernous hemangioma and receptor-positive carcinoid metastases.

## **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 radio-pharmaceutical. It is a kit consisting of two components:

- 1) A 10-mL OctreoScan Reaction Vial which contains a lyophilized mixture of 10 µg pentetreotide.
- 2) A 10-mL vial of Indium In-111 Chloride Sterile Solution.

Indium In-111 pentetreotide is prepared by combining the two kit components.



#### INDICATIONS AND USAGE

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

#### CONTRAINDICATIONS

None known.

#### WARNINGS

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

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

#### PRECAUTIONS

##### General

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

##### Carcinogenesis, Mutagenesis, Impairment of Fertility

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

##### Pregnancy Category C

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

##### Nursing Mothers

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

##### Pediatric Use

Safety and effectiveness in children have not been established.

#### ADVERSE REACTIONS

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

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

#### DOSAGE AND ADMINISTRATION

Before administration, a patient should be well hydrated. After administration, the patient must be encouraged to drink fluids liberally. Elimination of extra fluid intake will help reduce the radiation dose by flushing out unbound, labeled 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<sup>1</sup> 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 Kenning, et al.<sup>2</sup>

Estimated Absorbed Radiation Doses after Intravenous Administration of Indium In-111 Pentetreotide<sup>3</sup> 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 <sup>4</sup> 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. Kenning, 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. Kwekkaboom, A.E.M. Reij, 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-tyrosyl-L-threonyl-L-hemicystyl-L-threonyl cyclic (2-7) disulfide], (also known as octreotide DTPA),
  - (ii) 2.0 mg gentamicin [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.

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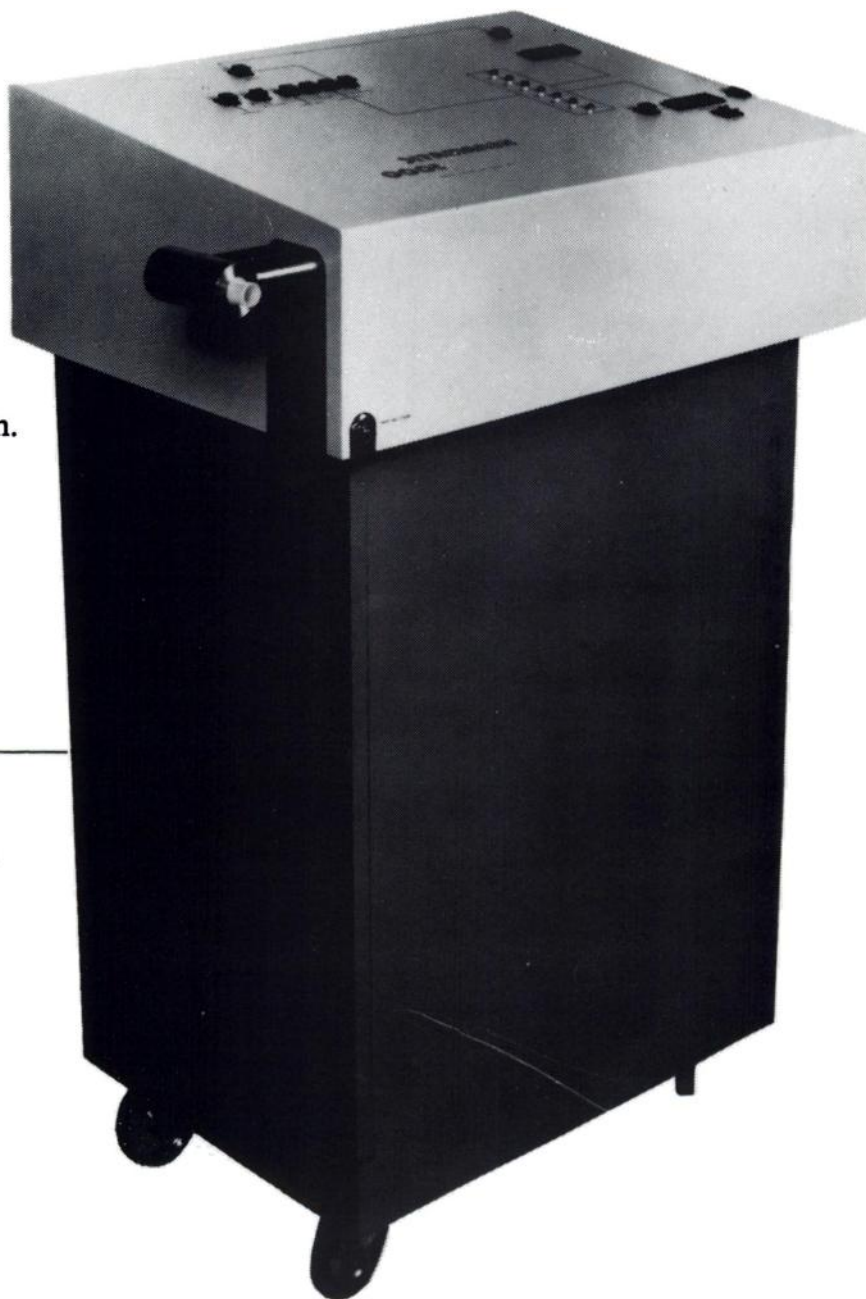
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- Rapid GI clearance

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### An efficient view.

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- Assessment of myocardial perfusion and ventricular function with a single injection
- Sensitive and reliable detection of coronary disease

### A patient's view.

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

 **Amersham HEALTHCARE**

See brief summary of prescribing information on following page

## Brief Summary



# Kit for the Preparation of Technetium Tc99m Tetrofosmin for injection

Diagnostic radiopharmaceutical For intravenous use only  
Code N166A

## DESCRIPTION

The Medi-Physics Myoview™ kit is supplied as a pack of five vials for use in the preparation of a technetium Tc99m tetrofosmin intravenous injection to be used for the scintigraphic delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium. Each vial contains a pre-dispensed, sterile, non-pyrogenic, lyophilized mixture of 0.23 mg tetrofosmin [6,9-bis(2-ethoxyethyl)-3,12-dioxo-6,9-diphosphatetradecane], 30 µg stannous chloride dihydrate (minimum stannous tin 5.0 µg; maximum total stannous and stannic tin 15.8 µg), 0.32 mg disodium sulphosalicylate and 1.0 mg sodium D-gluconate, and 1.8 mg sodium hydrogen carbonate. The lyophilized powder is sealed under a nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

**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 28-94 years). The subjects received a mean dose of 7.67 mCi on the first injection and 22.4 mCi on the second injection of Myoview.

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

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

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

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

## DOSAGE AND ADMINISTRATION

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

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

Imaging may begin 15 minutes following administration of the agent.

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

## RADIATION DOSIMETRY

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

Table 1

Estimated Absorbed Radiation Dose (Technetium Tc99m Tetrofosmin Injection)

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

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

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

Distributed by:

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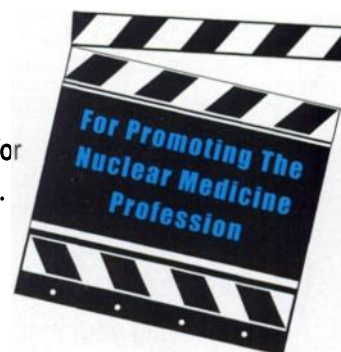


One of the goals of the Society Of Nuclear Medicine Technologist Section (SNM-TS) has been to take an active role in educating the public and the medical community about nuclear medicine procedures and the benefits of this functional imaging modality.

This is the official entry form for the 1996 PR Stars contest sponsored by the SNM-TS and Technology Imaging Services. Please fill out the information requested on the reverse side of this form. Based on this information, a panel of judges will evaluate the entries and select the winner. All entrants must be staff members of a hospital or Nuclear Medicine facility. Entries must be postmarked no later than December 16, 1996.

### Prizes:

- First Place:** \$1,000 for your institution; \$350 for the entrant; up to \$1,000 for airfare to the SNM 1997 Annual Meeting to accept your award.
- Second Place:** \$500 for your institution; \$250 for the entrant.
- Third Place:** \$250 for your institution; \$100 for the entrant.



### Entry Form:

Your Name \_\_\_\_\_

Hospital/Facility \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ Zip Code \_\_\_\_\_

Telephone/ Fax \_\_\_\_\_

### Mail or Fax by December 16, 1996 To:

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**P.O. Box 3589**  
**Youngstown, Ohio 44513**  
**Fax: (330) 758-1617 Tel: (800) 409-2688**  
**Attn: Jenny O'Kane, Vice President**



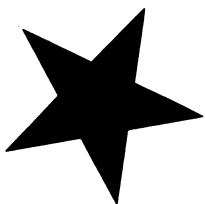
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Documentation of your activities is encouraged and may be mailed with your entry. (All original materials will be returned after judging has been completed.) You may also use additional pages as necessary.

- 1 Describe your Nuclear Medicine Week activities:
  - a. When did you celebrate? \_\_\_\_\_
  - b. What was your primary objective or message? \_\_\_\_\_
  - c. Who was your target audience? \_\_\_\_\_
- 2 What available resources did you use? (budget, manpower, media, etc.) \_\_\_\_\_
- 3 Describe your success in achieving your primary objective, hitting your target audience or successfully conveying your message. Include the most notable aspects and/or anecdotes. \_\_\_\_\_
- 4 Did your celebration have any positive outcome(s)? \_\_\_\_\_
- 5 Finally, can you offer the Nuclear Medicine Week Committee any suggestions for improving our materials or contest? \_\_\_\_\_



Thank you for your entry, and GOOD LUCK!

Patti Corrigan, C.N.M.T.  
Nuclear Medicine Week Chairperson





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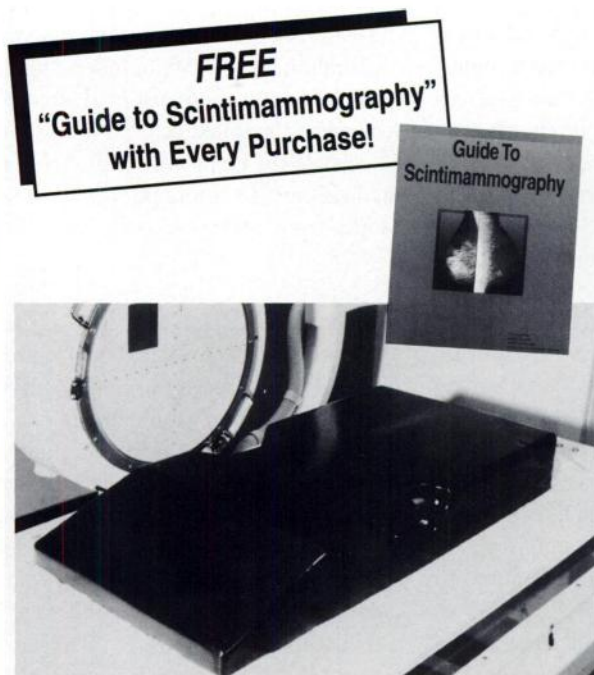
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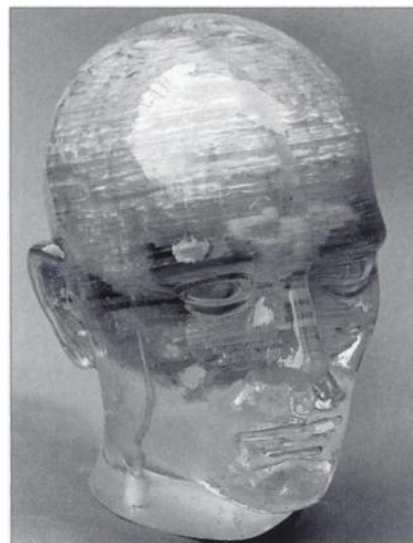
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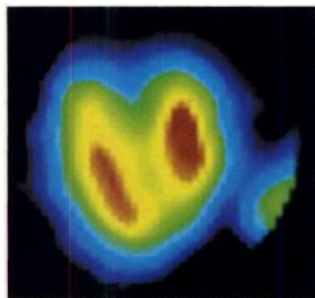


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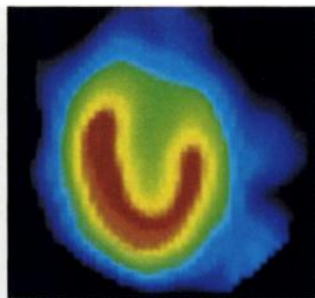
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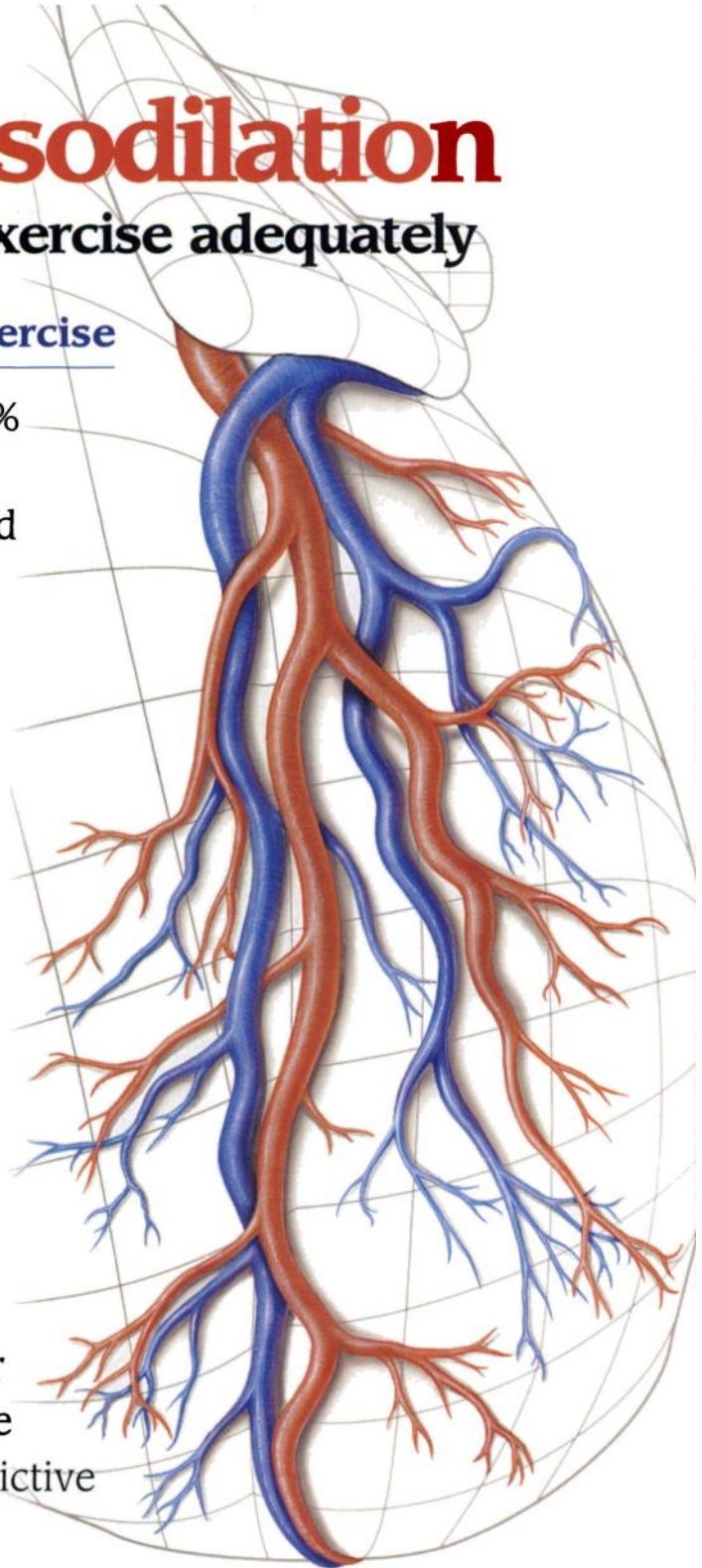


Redistribution

## Rapid onset, short duration

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

Contraindicated in patients with 2nd- or 3rd-degree AV block, sinus node disease and known or suspected bronchoconstrictive or bronchospastic lung disease.



# ADENOSCAN<sup>®</sup>

---

## 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

### 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 8.3% 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 reflex 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 (V<sub>E</sub>) and reduce arterial PCO<sub>2</sub> causing respiratory alkalosis. Approximately 28% 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 diseases. Adenoscan should be used with caution in patients with obstructive lung diseases 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 alkyloxanthines (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<sup>2</sup> 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	28%	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.

**Notes:** 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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adenosine

Visit us at RSNA booth #5015

Each description of the products below was condensed from information supplied by the manufacturer. The reviews are published as a service to the professionals working in the field of nuclear medicine and their inclusion herein does not in any way imply an endorsement by the Editorial Board of *The Journal of Nuclear Medicine* or by the Society of Nuclear Medicine.

### Liquid Scintillation Counter Suitable for *Helicobacter pylori* $^{14}\text{CO}_2$ Breath Tests



Packard Instrument Company announces the Tri-Carb<sup>®</sup> model 2100TR liquid scintillation analyzer which is ideally suited for counting the samples and analyzing the results of  $^{14}\text{CO}_2$  breath tests, such as for *Helicobacter pylori* and triolein fat tests. The Tri-Carb 2100TR is a full capability liquid scintillation counter (LSC), featuring built-in 486SLC computer control. TR-LSC background reduction is standard on the 2100TR, providing the highest sensitivity (signal-to-noise ratio) of any low cost, full function LSC, to ensure the maximum sensitivity for differentiating between

positive and negative *Helicobacter pylori* test results.

When equipped with the automatic tandem processing option and >500 MB built-in hard disk, the Tri-Carb 2100TR is capable of providing unattended, on-line data processing of *Helicobacter pylori* and other radioisotope test results, including the possibility of generating customized patient reports. When equipped with the optional built-in network card, the 2100TR can be connected to virtually any network to automatically transmit count data, or even completed reports, to a mainframe computer or another work station on the network.

The Tri-Carb 2100TR standard features include: automatic instrumental performance assessment to help ensure GLP compliance, the highest 20-ml vial sample capacity of any commercially available LSC and the most positive sample identification available, including an optional work list feature that can be appended to the sample data file for accurate sample archiving. **Packard Instrument Company, 800 Research Parkway, Meriden, CT 06450. Phone: (203) 238-2351. Fax: (203) 639-2172.**

### Toshiba's Nuclear Medicine Systems Feature New Computer Platform

The dual-head GCA-7200A/DI and the single-head GCA-7100A/DI nuclear medicine gamma camera systems from Toshiba feature an improved computer platform. The two systems incorporate two Super-SPARC CPUs which provide a powerful base for nuclear medicine image processing. The dedicated graphics processor capably handles high-speed cine displays and requirements for real-time zoom. Easily understood icons and pull-down menus make for a user-friendly processing system. This combination also ensures smooth, quick execution of all software commands providing for increased clinical productivity.

A local area network (LAN) communications link can be established between other Toshiba gamma cameras, the GMS-5500A/DI workstation and digital laser images or color printers. Other Toshiba gamma camera include the rectangular large-field detectors (550 × 400 mm; 21.7" ×

15.7") that provide fast, more complete coverage of any portion of the patient's body. Whole-body scanning, SPECT and planar imaging are accomplished quickly with a minimum of operator involvement. The short distance (63 mm; 2.52") between the edge of the field of view and the detector casing makes imaging of the entire brain routinely possible. Fan-beam collimators are available for high-resolution brain SPECT.

The GCA-7200A/DI and GCA-7100A/DI systems also allow for autopositioning. When the operator pushes a button, the system automatically measures body thickness and adjusts the table height to center the patient to the detector. The autopositioning functions also enhance the ease of collimator exchange and reduce camera set-up time. Also, adjustable table height allows for easier access by patients and operators. **Toshiba America Medical Systems Inc., 2441 Michelle Dr., Tustin, CA 92681-2068. Phone: (714) 669-4140.**



### SmartDocs<sup>™</sup>: Accurate Billing for Hospital Rounds

SmartDocs from Berdy Medical Systems is a software program that helps physicians keep track of patient information. With SmartDocs, physicians now have a convenient method to capture patient information, diagnoses and procedures on a hand-held computer. The product runs on a small computer that conveniently fits in either a lab or breast coat pocket (computer size: 6.5" × 3.3" × 0.9"; weight: 11 ounces). There are no complicated codes or hard to remember commands—just press a key and go. Both the software and computer are being sold directly by Berdy Medical Systems for \$620. SmartDocs is designed for the computer novice.

The Berdy SmartDocs package includes the Psion Series 3a, which is a powerful pocket-sized computer. This versatile personal digital assistant has built-in features that include: a word processor, spreadsheet, data manager, appointment scheduler, voice recorder and more. After recording your diagnosis and visit information on the spot you can print them out or display them for entry into the office billing system at a later time. SmartDocs helps you find the right codes so your billing and records are more accurate. Thus, penalties associated with errant billing are avoided. All evaluation and management current procedural terminology codes and the top international classification of disease codes are preloaded and easy to locate. A find feature allows for a key word search for the desired code for fast access. **Berdy Medical Systems Inc., Mack Centre 1, 365 West Passaic St., Rochelle Park, NJ 07662-3012. Phone: (201) 843-3366. Fax: (201) 843-0364.**





ANNOUNCING

**The American  
Board of  
Science in  
Nuclear  
Medicine  
1997  
Certification  
Examination**

**The 1997 examination will be given Sunday,  
June 1, 1997 in San Antonio, Texas  
in conjunction with the 44th Annual Meeting of the  
Society of Nuclear Medicine.**

The examination is written and consists of two parts —

**Part One** (3.5 hours) assesses knowledge of basic aspects of Nuclear Medicine Science.

**Part Two** (2.5 hours) examines in depth the knowledge of a predetermined subspecialty area of the candidate's choice including:

- Nuclear Medicine Physics and Instrumentation
- Nuclear Pharmaceutical Science and Radiochemistry
- Radiation Protection

**Completed Applications must be postmarked by March 14, 1997.  
The examination fee is \$450 (\$400 refundable if you do not qualify).**

For applications and more information, please contact:

Joanna Wilson, Associate Coordinator

American Board of Science in Nuclear Medicine

c/o The Society of Nuclear Medicine

1850 Samuel Morse Drive, Reston, Virginia 20190-5316

Tel: (703) 708-9000, ext. 250 • Fax: (703) 708-9015

**SNM  
44<sup>TH</sup> ANNUAL MEETING  
*Critical Dates***

<b>Item</b>	<b>Due Date</b>
<b>ABSTRACT FORMS</b>	
Scientific Papers . . . . .	October Issue JNM . . . . . 1/9/97
Scientific Exhibits . . . . .	October Issue JNM . . . . . 1/9/97
<b>REGISTRATION FORM</b> . . . . .	<b>Contact:</b> . . . . . 4/28/97
<b>HOUSING FORM</b> . . . . .	<b>Dept. Meeting Services</b> . . . . . 5/2/97

**DON'T FORGET THE MID-WINTER MEETING IS IN PALM SPRINGS, CALIFORNIA**

**DATE:** February 5-11, 1997

**LOCATION:** The Palm Springs Riviera Resort and Racquet Club

**EDUCATION PROGRAM SPONSOR:** The Computer and Instrumentation Council



or PhD)] in nuclear medicine for his/her accomplishments. Applications must include curriculum vitae, a statement detailing research accomplishments and future goals, three or more letters of recommendations from established investigators, and up to three selected reprints. Application deadline: March 1, 1997.

**Paul D. Cole Scholarships**—Established by the SNM-Technologist Section and the family and friends of Paul D. Cole, twelve \$1000 scholarships, one for each of the three types of nuclear medicine technology training programs (certificate, associate, baccalaureate) are available for qualified applicants. Application deadline: May 1, 1997.

#### Awards and Fellowships Sponsored by the Society of Nuclear Medicine and Other Organizations

**DuPont Pharma Nuclear Oncology and Nuclear Cardiology Research Fellowships**—The Society of Nuclear Medicine Awards Committee announces two fellowships; one for \$10,000 in nuclear oncology and one for \$20,000 in nuclear cardiology. The fellowships will be available July 1, 1997. The objective of the nuclear oncology fellowship is to support high quality research in the area of <sup>99m</sup>Tc-labeled compounds for breast imaging as a complement to Mammography. The objective of the Nuclear Cardiology fellowship is to support high quality clinical research in any of the following areas: gated SPECT, heart failure, CAD prognosis or CAD in women. Both fellowships' goal is to encourage new entrants into the fields of nuclear oncology and nuclear cardiology. The awards will be announced at the Annual SNM Meeting in June, 1997 in San Antonio, TX. For more information and an application contact: Society of Nuclear Medicine, SNM Awards Committee, 1850 Samuel Morse Dr., Reston, VA 20190-5316. Application deadline: January 6, 1997.

**Mallinckrodt Fellowship**—Mallinckrodt, Inc. announces its annual fellowship of \$30,000 for a physician fellow active in nuclear medicine research and/or development. The award is to further a research project involving the development of single photon radiopharmaceuticals or beta emitters to be used in nuclear medicine oncology. Applicants are asked to submit their curriculum vitae, a detailed account of their research project including prior accomplishments on the project and

future plans. Requested information, along with at least two letters supporting the application, should be forwarded to: William J. MacIntyre, PhD, Society of Nuclear Medicine, 1850 Samuel Morse Dr., Reston, VA 20190-5316. Nomination deadline: January 6, 1997.

**Paul C. Aebersold Award**—Applications are invited for the Paul C. Aebersold Award for outstanding achievement in basic science applied to nuclear medicine. This award commemorates the contributions of Dr. Paul Clarence Aebersold to the applications of nuclear physics to nuclear medicine and radiation biology, as well as his contributions to the Society of Nuclear Medicine. Dr. Aebersold contributed greatly to the emergence of nuclear medicine as a discipline by his energetic leadership in the provision of cyclotron-generated and reactor-produced radionuclides, and by his numerous publications and lectures. In giving this award, the Society thus symbolically signifies its appreciation of the warm and vital person who became the Society's first Honorary Member. Nominations should be supported by the nominee's curriculum vitae and at least two letters supporting the nomination. These letters should briefly describe the contributions in basic science for which the nominee is proposed. The nominee does not need to be a SNM member. Nomination deadline: December 31, 1996. Please submit nominations and supporting documents to: William J. MacIntyre, PhD, c/o Society of Nuclear Medicine, 1850 Samuel Morse Dr., Reston, VA 20190-5316.

#### SNM MEETING DATES AND VENUES

##### 44th Annual Meeting

June 2-5, 1997  
San Antonio  
Convention Center  
San Antonio, TX

##### 45th Annual Meeting

June 7-11, 1998  
Toronto Convention Center  
Toronto, Canada

##### 46th Annual Meeting

June 6-10, 1999  
Los Angeles Convention Center  
Los Angeles, CA

#### SNM HELP LINE (703) 708-9000

- For SNM membership questions or how to obtain a subscription to SNM journals, contact: Shai Lazarte, ext. 232 or e-mail her at [slazarte@snm.org](mailto:slazarte@snm.org).
- For information on obtaining VOICE credits, contact: Marcia Ferg, ext. 210 or e-mail her at [mferg@snm.org](mailto:mferg@snm.org).
- For questions pertaining to continuing education credits or your state requirements, contact: Marcia Ferg, ext. 210 or e-mail her at [mferg@snm.org](mailto:mferg@snm.org).
- To order the pocket lecture series, contact: National Audio Visual (800) 373-2952. Fax: (303) 292-5629.

- To order patient pamphlet brochures for your hospital or university, contact: Matthews Medical Books (800) 633-2665 or (314) 432-1401.

- To order SNM books or single-copy issues of *The Journal of Nuclear Medicine* or the *Journal of Nuclear Medicine Technology*, contact: Matthews Medical Books (800) 633-2665 or (314) 432-1401.

- For questions on any SNM publication or how to obtain sample SNM pamphlets, contact: Stacey Silver, ext. 223 or e-mail her at [ssilver@snm.org](mailto:ssilver@snm.org).

- For classified advertising space and price quotes, contact: Jessica McLane Petit, ext. 226 or e-mail her at [jmclane@snm.org](mailto:jmclane@snm.org).

- For permission requests on articles or figures appearing in either *The Journal of Nuclear Medicine* or the *Journal of Nuclear Medicine Technology*, contact: Dawn Murphy, ext. 211 or e-mail her at [dmurphy@snm.org](mailto:dmurphy@snm.org).

- For questions concerning adverse drug reactions to radiopharmaceuticals, contact: USP Drug Reports (800) 638-6725.

- SNM home page address: <http://www.snm.org>.

- For bulk reprints, contact: Steve Klein, ext. 213 or e-mail him at [sklein@snm.org](mailto:sklein@snm.org).

# INTRODUCING THE MOST UP-TO-DATE SELF-ASSESSMENT PROGRAM ON INSTRUMENTATION

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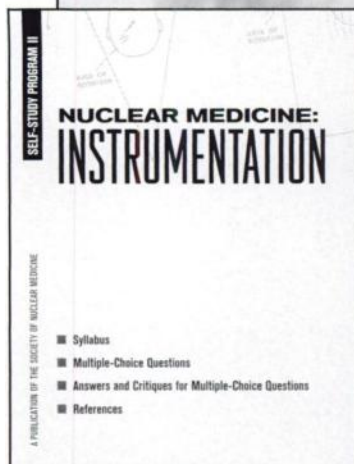
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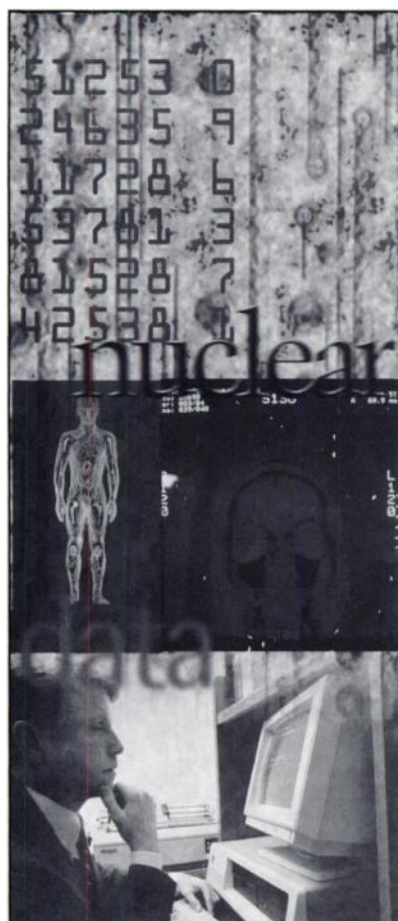
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## NUCLEAR MEDICINE: INSTRUMENTATION

- Syllabus
- Multiple-Choice Questions
- Answers and Critiques for Multiple-Choice Questions
- References



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# DATA MANAGEMENT IN NUCLEAR MEDICINE

## LOCATION AND DATES

**Palm Springs Riviera Resort and Racquet Club**  
Monday, February 10, through Tuesday, February 11, 1997

Call SNM Department: Meeting Services  
703-708-9000

	Before 1/14/97	On/After 1/14/97
<b>Physicians/Scientists</b>		
Members	\$185.00	\$230.00
Nonmembers	\$215.00	\$260.00
<b>Technologists</b>		
Members	\$90.00	\$120.00
Nonmembers	\$120.00	\$150.00
Students	\$70.00	\$70.00



The 1997 Scientific Program Committee, Scientific Exhibits Subcommittee and the Scientific & Teaching Sessions Committee solicit the submission of abstracts

from members and nonmembers of the Society of Nuclear Medicine for the 44th Annual Meeting in San Antonio, TX. Accepted Scientific Paper and Scientific Exhibit abstracts will be published in a special supplement to the May issue of *The Journal of Nuclear Medicine* and accepted Technologist Section abstracts will be published in the June issue of the *Journal of Nuclear Medicine Technology*. Original contributions on a variety of topics related to nuclear medicine will be considered, including:

- Instrumentation and Data Analysis
- Radioassay
- Radiopharmaceutical Chemistry

## CALL FOR ABSTRACTS FOR SCIENTIFIC PAPERS AND SCIENTIFIC EXHIBITS

the Society of  
Nuclear Medicine

**44<sup>th</sup>**

Annual Meeting

June 1- June 5, 1997

San Antonio, Texas

- Dosimetry/Radiobiology
- Clinical Science Applications:
  - Bone/Joint
  - Cardiovascular (clinical, basic, and PET)
  - Endocrine
  - Gastroenterology
  - Neurosciences: Basic, Neurology and Psychiatry
  - Pediatrics
  - Pulmonary
  - Renal/Electrolyte/Hypertension
  - Hematology/Infectious Disease
  - Oncology Diagnosis (antibody)
  - Oncology Diagnosis (non-antibody)
  - Oncology/Therapy

Authors seeking publication for the full text of their papers are strongly encouraged to submit their work for immediate review to JNM, and for the technologist section, to JNMT.

The Scientific Paper and Exhibit abstract form can be obtained in the September and October 1996 JNM. You can also obtain an abstract form by writing to:

Society of Nuclear Medicine  
Att: Abstracts  
1850 Samuel Morse Drive  
Reston, VA 20190  
Tel: (703)708-9000  
Fax: (703)708-9015  
<http://www.snm.org>

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IS THURSDAY, JANUARY 9, 1997.

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## Position Available

### Brain SPECT Imaging Fellowship

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@uabdp.dpo.uab.edu (UAB is an Affirmative Action/Equal Opportunity Employer).

### Cyclotron Operator/Maintenance

The Department of Radiology is looking for a dependable, well-organized individual to join the Cyclotron Facility. We operate a JSW 3015 machine for production of short-lived radioisotopes for PET studies. Candidates must have a BS degree in physics, engineering or related science and good mechanical and electrical skills. Prior experience highly desirable. Duties include daily operation of cyclotron, targets and related equipment. Routine maintenance and troubleshooting. Design and implementation of new remote systems and upgrades of existing components. Collaborate with investigators in research projects. Salary commensurate with experience and educational background. Includes a comprehensive benefits package. Send resume to: Dr. Carlos Gonzalez, Dept. of Radiology - I Silverstein, University of Pennsylvania, Philadelphia, PA 19104-4283. AA/EOE. <http://www.upenn.edu/hr>

### Diagnostic Radiology Residency

First-year Diagnostic Radiology residency position available for 1997 at a large, level I trauma center and active 450-bed municipal hospital in San Jose, California. Candidates must have completed one year of internship prior to acceptance. Send CV and applications to: Ms. Vickie Higgins, Dept. of Radiology, Santa Clara Valley Medical Center, San Jose, CA 95128. Phone: 408-885-6370.

### Director of Nuclear Medicine Physics

Emory University, Division of Nuclear Medicine is recruiting a physical scientist for a full-time tenure track faculty position. Applicants must possess a PhD in Medical Physics, Biomedical Engineering, Computer Science or a related field, two years experience in nuclear medicine and demonstrated ability to obtain extramural funding. Responsibilities include physics, computer and instrumentation support to nuclear medicine including ongoing research and teaching residents. This scientist is expected to develop an independent grant funded program in nuclear medicine research. Unique research opportunity exists in collaboration with the Emory PET Center, in the development and validation of high-energy imaging techniques with hybrid SPECT sys-

tems. Academic rank and salary will be commensurate with experience. Forward CV to: Andrew Taylor, MD, Division of Nuclear Medicine, (Rm. E121), Emory University Hospital, 1364 Clifton Road, NE Atlanta, GA 30322. Emory University is an EOE/AA employer.

### Division Head of Nuclear Medicine

The Department of Radiology, Division of Nuclear Medicine at Vancouver Hospital & Health Science Center is seeking a Head for the Division of Nuclear Medicine. This position will carry a part-time appointment with the University of British Columbia, rank and salary subject to qualifications and experience. This senior person must be certifiable to practice nuclear medicine in British Columbia. Responsibilities will include Head, Division of Nuclear Medicine, Vancouver Hospital & Health Sciences Center, and they will be expected to take an active role in teaching. As well, they must have proven research experience and it is desirable if this includes PET. The successful candidate will be joining two other nuclear medicine physicians in a practice which contains eight cameras, two bone density units and is totally networked. All aspects of nuclear medicine are currently practiced. There is also support for a Basic Science Division with physicists and a radiopharmacist. The expected start date of this appointment is July 1, 1997. The University of British Columbia welcomes all qualified applicants, especially women, aboriginal people, visible minorities and persons with disabilities. In accordance with Canadian Immigration requirements, this advertisement is directed to Canadian citizens and permanent residents. Send curriculum vitae and names of three references to: Dr. B. Lentle, Head, Department of Radiology, Vancouver Hospital & Health Sciences Center, 855 West 12th Ave., Vancouver, BC V5Z 1M9. The deadline for closing this competition is February 1, 1997.

### Nuclear Medicine Physician

Active, affiliated VA Medical Center is seeking BC/BE physician to join our nuclear medicine staff. Competitive salary and benefits. Excellent location and diverse outdoor recreational opportunities. Send resume to: Patrick McDaniel, Human Resources (05C), VA Medical Center, 2200 Fort Roots Drive, North Little Rock, AR 72114. Phone: 501-370-6683. EOE.

### Nuclear Medicine Physician

The Dept. of Radiological Sciences of the University of Oklahoma Health Sciences Center has an opening for a staff radiologist with specialization in nuclear medicine. Faculty rank and remuneration will depend on credentials and experience. Members of the nuclear medicine section provide coverage for the University Hospital (adult), Children's Hospital of Oklahoma and the DVA Medical Center in Oklahoma City. The section is well-equipped and performs approximately 10,000 studies/yr in aggregate. The individual selected will have primary responsibilities in one of the adult units, but will be expected to provide cross coverage within the other units. In addition, the individual will spend at least one day a week covering other areas of radiology and will be included in radiology on-call coverage. If interested, please contact: Joe C. Leonard, MD, Chief, Pediatric Imaging Service, Children's Hospital of Oklahoma, P.O. Box 26307, Oklahoma City, OK 73126.

### Nuclear Medicine Residency

July 1997. Comprehensive imaging/RIA/therapy program in 4 hospitals (private, county, VA) with 2500 total

beds. Mobile imaging for over 200 ICU beds. Large pediatric population. Strong cardiovascular emphasis. State-of-the-art instrumentation including SPECT computer processing. Once year of ACGME-approved preparatory residency required prior to entry. Contact: Warren H. Moore, MD, Department of Radiology, Baylor College of Medicine, One Baylor Plaza, Houston, TX 77030. Baylor College of Medicine is an EO/AA employer.

### PET Fellowship

Research fellowship in PET at the Northern California PET Imaging Center affiliated with the University of California at Davis, for one year starting 7/1/97. Active clinical and research facility, 800 studies per year in oncology, neurology and cardiology. BC/BE applicant expected to participate in interpretation of studies, oncologic PET research, presentation of results and teaching. Please send curriculum vitae to: Peter E. Valk, MD, Northern California PET Imaging Center, 3195 Folsom Blvd., Sacramento, CA 95816.

### Postdoctoral Research Fellowship (MD, PhD): Cancer Imaging (UCSF and LBNL)

Two-year research training fellowship in diagnostic oncology imaging. Research training focuses on NMR imaging and spectroscopy, as well as emission tomography (PET and SPECT). Equipment includes state-of-the-art MRI, PET and other imaging devices and laboratory facilities at the UCSF Department of Radiology and at the Lawrence Berkeley National Laboratory Center for Functional Imaging. Trainees work under direct guidance of a faculty preceptor. Program funded by the National Cancer Institute (T32 CA 66527). Minorities and women are encouraged to apply. Send inquiries to: Randall A. Hawkins, MD, PhD, Department of Radiology, University of California, San Francisco, (UCSF), 505 Parnassus Ave., San Francisco, CA 94143-0252. Phone: 415-476-1521. E-mail: randy\_hawkins@rad-mac1.ucsf.edu.

## Position Wanted

ABNM certified, young physician with expertise in all clinical aspects of nuclear medicine seeks a temporary or permanent, part-time or full-time employment in a Veterans administration hospital beginning immediately. Phone: 210-616-5311.

Nuclear medicine physician, took ABNM Sept. 1996, strong IM background, experienced in all aspects of diagnostic, therapeutic (I 131, SR89) NM including cardiac SPECT and oncology. Please respond to: Society of Nuclear Medicine, Box #1101, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

ABNM and general surgery board certified physician seeks a full-time nuclear medicine position. Would consider a combination general surgery and nuclear medicine practice for the right opportunity. Willing to relocate. Experienced in all aspects of nuclear medicine including PET. Expertise in nuclear medicine departmental development. Excellent clinical rapport with referring physicians resulting in increased departmental productivity. Please reply to the Society of Nuclear Medicine, Box #1102, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

# JNM

## DIRECT RESPONSE Advertisers for November 1996

Listed below are the companies that have advertised in this issue. Simply circle the numbers of those companies you are interested in, fill out the information below, and mail or FAX this to the Society of Nuclear Medicine, Advertising Department, 1850 Samuel Morse Drive, Reston, VA 20190, Fax 703-708-9015. We will forward this information to the advertiser(s).

Reader Svc.No.	Advertiser		Telephone No.	Page(s)
1	ADAC Laboratories	Milpitas, CA	800/538-8531	Special Insert 17A-20A
10	Amersham, Medi-Physics, Inc.	Arlington Heights, IL	708/593-6300	35A - 36A
11	Bicron Corp.	Newbury, OH	216/564-2251	25
23	Capintec, Inc.	Ramsey, NJ	800/631-3826	2A
31	Data Spectrum	Chapel Hill, NC	919/732-6300	27A
32	Diversified Diagnostics	Houston, TX	713/955-5323	33A
34	Du Pont Company	No. Billerica, MA	800/343-7851	14A-16A
42	Elscent, Ltd.	Hackensack, NJ	800/228-7226	Inside Back Cover
50	Fujisawa USA, Inc.	Deerfield, IL	708/317-8633	45A-46A
82	Immunomedics	Morris Plains, NJ	800/327-7211	13A
110	Mallinckrodt Medical, Inc.	St. Louis, MO	314/895-2000	9A -12A and 28A-30A
131	Nuclear Associates	Carle Place, NY	516/741-6360	39A
132	North American Scientific	N. Hollywood, CA	818/503-9201	41A
133	Nuclemed	Belgium	051-22-1746	41A
140	Ones Medical Services	Goffstown, NH	800/438-6637	41A
151	Picker International	Cleveland, OH	216/475-1111	4A-5A
181	Siemens Medical Systems, Inc.	Hoffman Estates, IL	708/304-7252	Inside Front Cover and 1A
192	Toshiba Medical Systems	Tustin, CA	800/521-1968	Back Cover
211	Victoreen	Cleveland, OH	216/248-9300	39A

☐ SNM Meetings ☐ SNM Membership Information ☐ SNM Book Order Information

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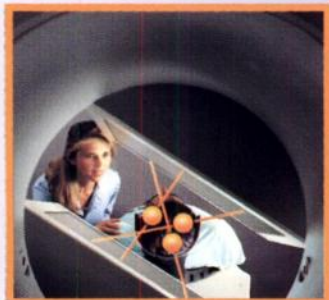
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# VariCam *Get an angle on the future...*



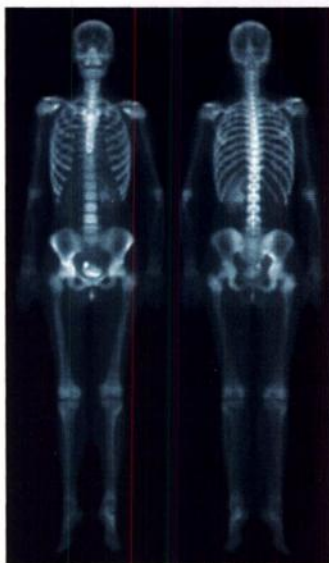
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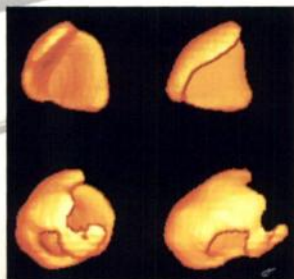
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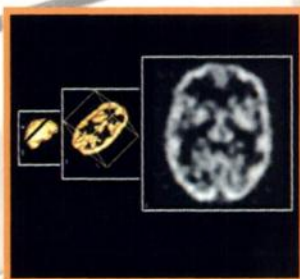


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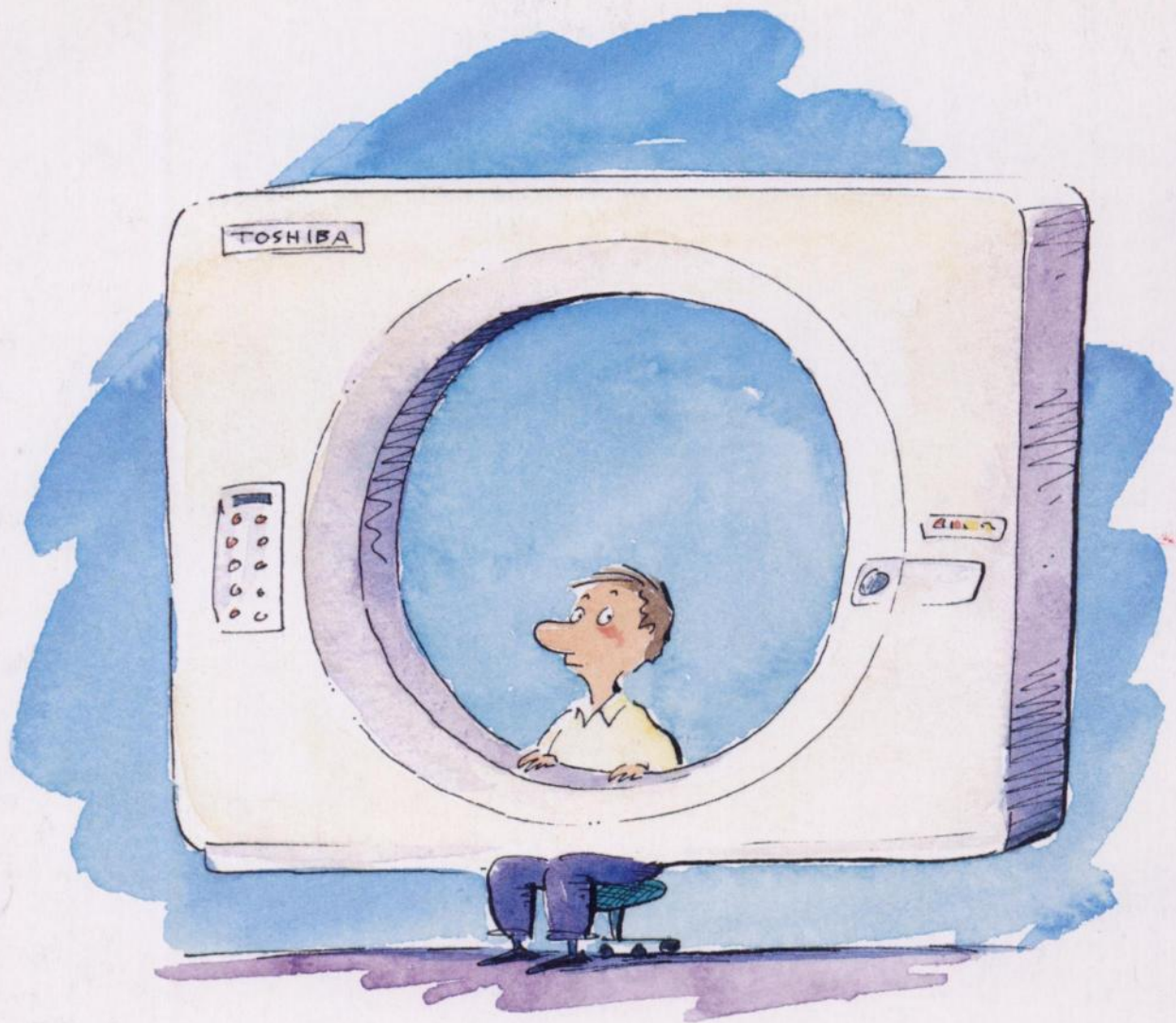
# **Elscint**

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