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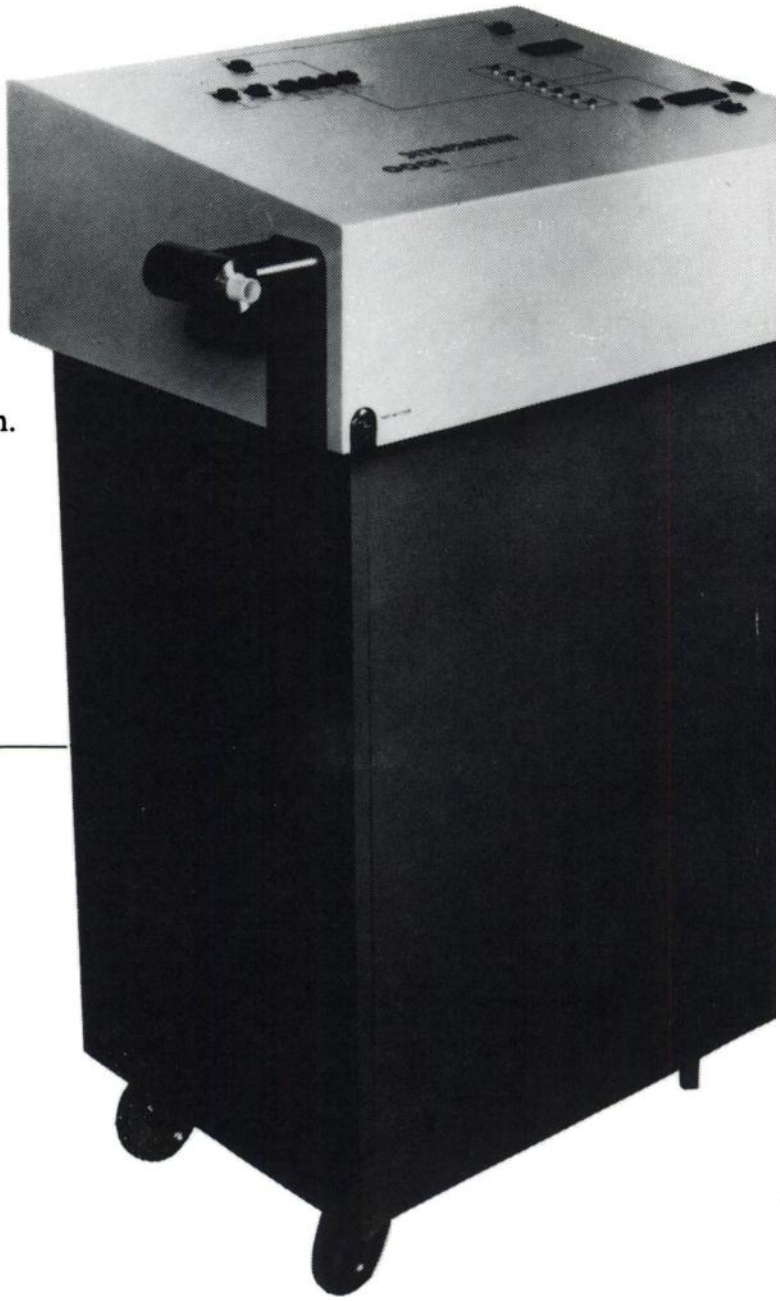

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SIEMENS

ECAT
Positron Emission Tomography

Case Study NM

Identifying Ischemic but Viable Myocardium

Courtesy of
Dr. Myrwood C. Besozzi
The University of Tennessee
Medical Center at Knoxville

History:

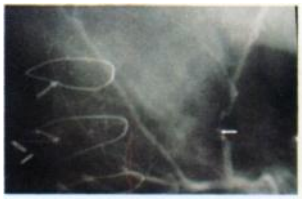
A 56-year-old male complaining of chest pain was examined. Earlier, this patient had experienced a heart attack which infarcted certain sections of the myocardium. The patient underwent a coronary artery bypass graft (CABG) to the right artery and the left anterior descending artery.

Since the pain suggested the development of ischemic myocardium, a coronary arteriogram and ECAT® PET study were conducted. (An ECAT PET study with an exercise protocol determines focal areas of ischemic but viable tissue, thereby identifying tissue which is potentially salvageable with surgery or with balloon angioplasty to open the blocked artery.)

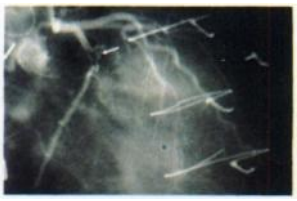
Study Findings:

CATH

A coronary arteriogram demonstrated 100 percent blockage in the distal portion of the left anterior descending artery.



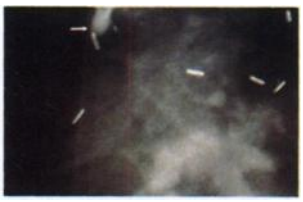
CATH



CATH

PET

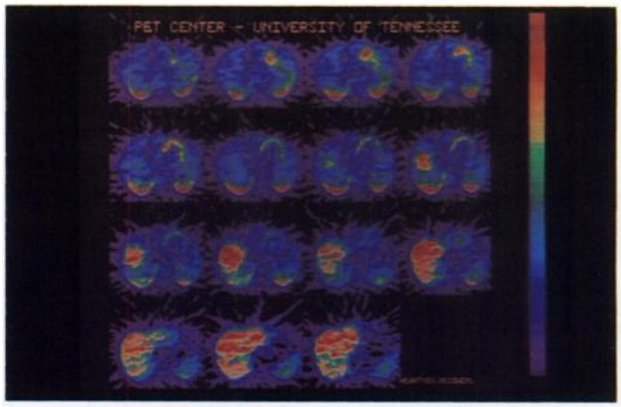
Two ECAT PET scans were conducted: a $^{13}NH_3$* perfusion scan and an ^{18}FDG* muscle viability scan. The normal $^{13}NH_3$ perfusion scan and ^{18}FDG uptake indicated the heart muscle was receiving sufficient oxygen.



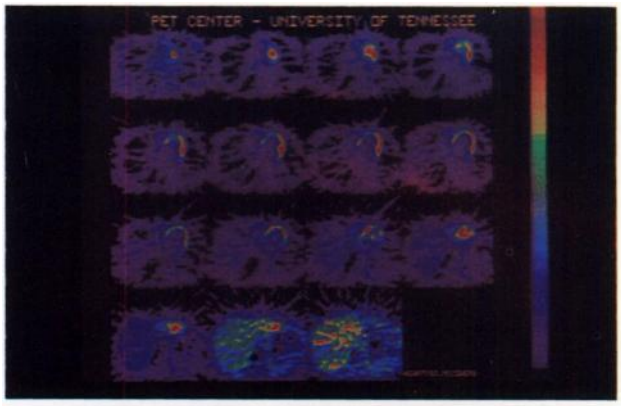
CATH

Treatment:

Since the PET scan demonstrated that the heart was receiving sufficient oxygen, bypass surgery was not indicated. Instead, this patient was placed on an appropriate program of medical care.



PET-$^{13}NH_3$



PET-^{18}FDG

*$^{13}NH_3$ and ^{18}FDG have not received FDA approval.

Note: Of necessity, original images always lose a certain amount of detail when reproduced.

CASE STUDY UT 1C

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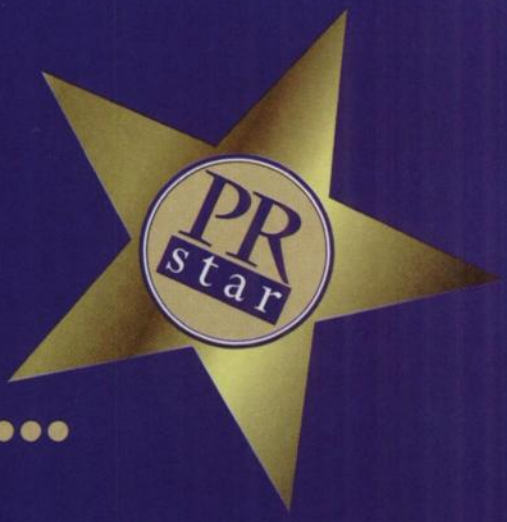

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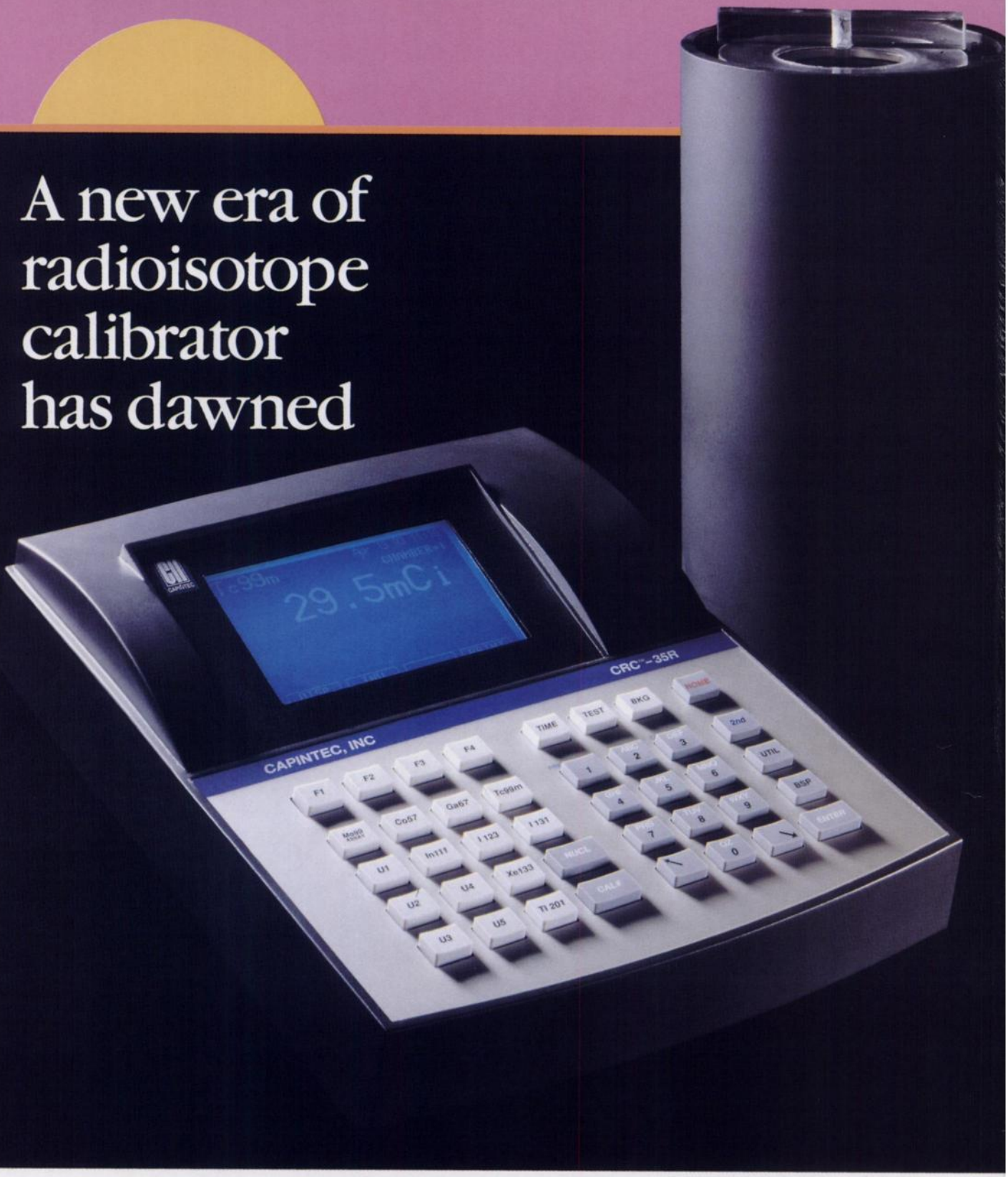

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- **"Detection of Cerebrovascular Disease with Diamox/HMPAO Scintigraphy,"** Jack Juni, *William Beaumont Hospital, Royal Oak, MI.*
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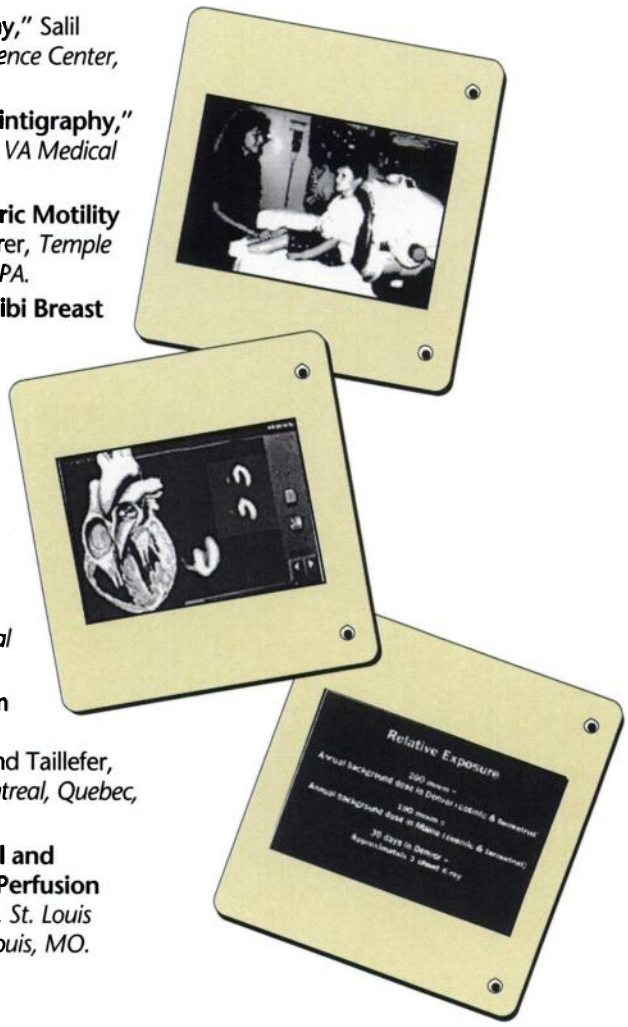
- **"Combined Functional and Perfusion Myocardial Perfusion Imaging,"** Mark Wittry, *St. Louis University Hospital, St. Louis, MO.*



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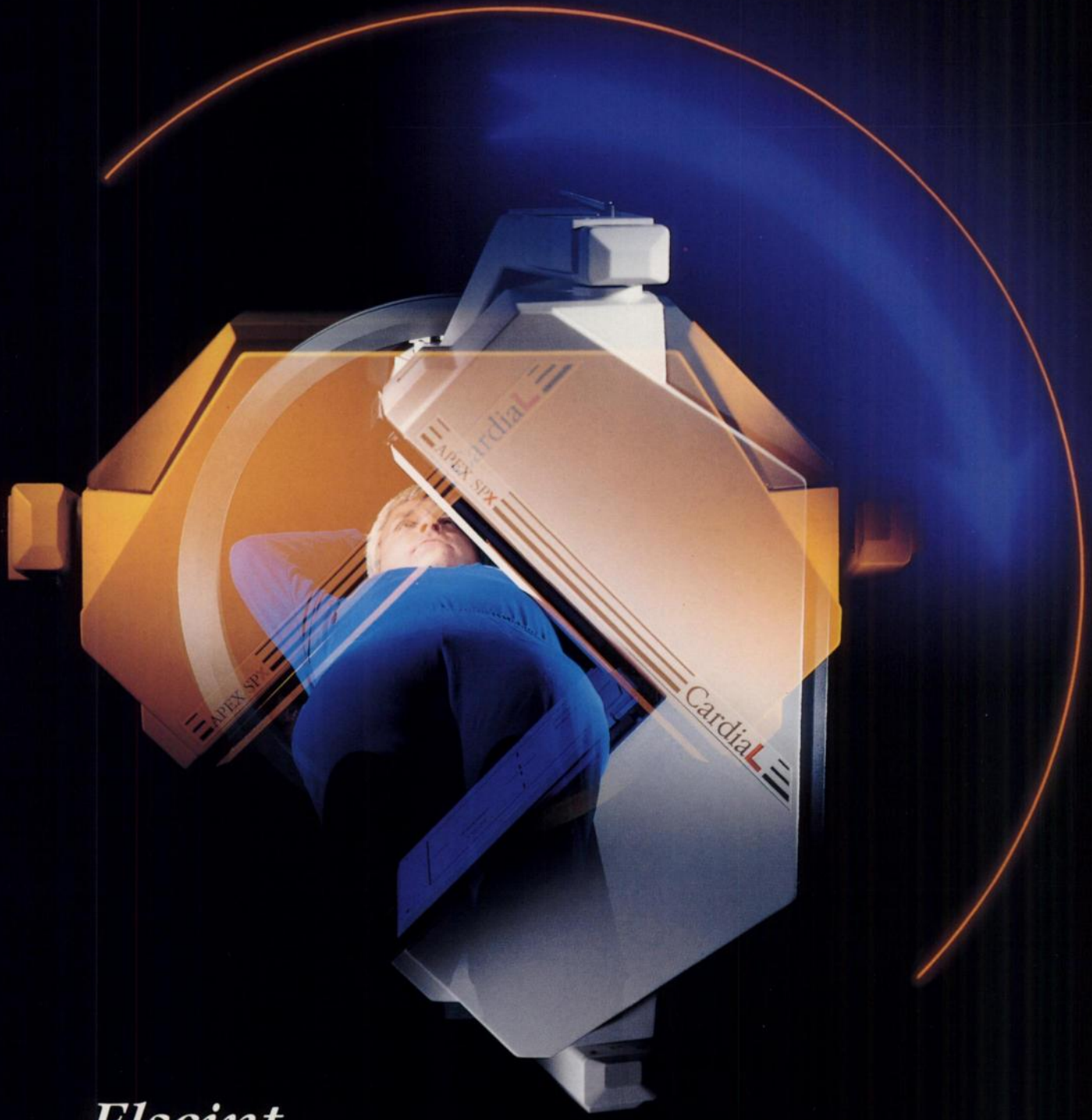

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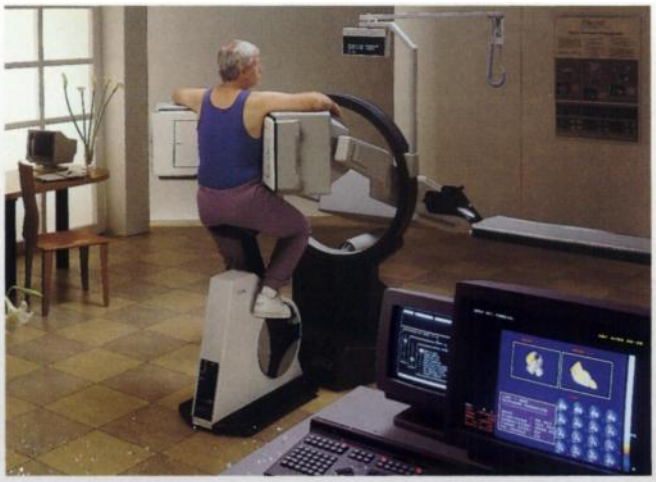
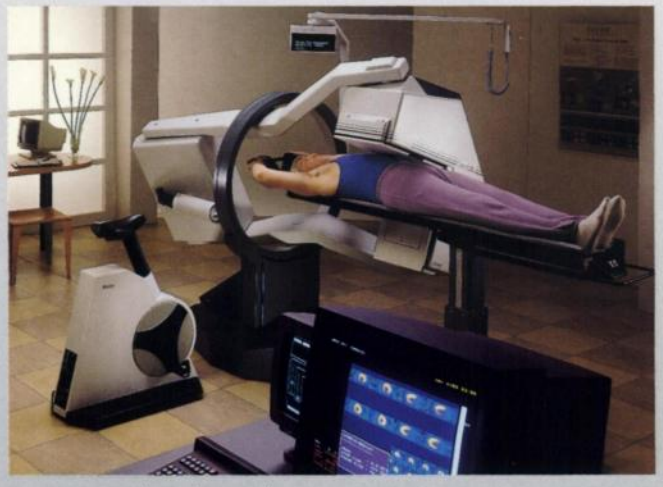


Instant shift from upright exercise...



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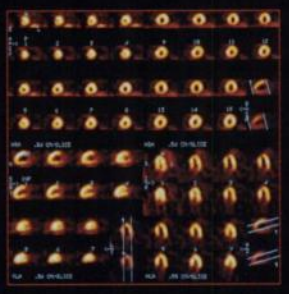
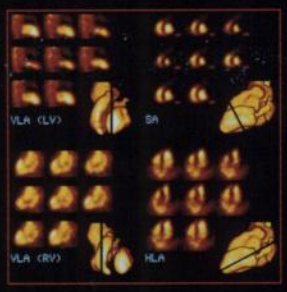
Sestamibi 3D surface-map



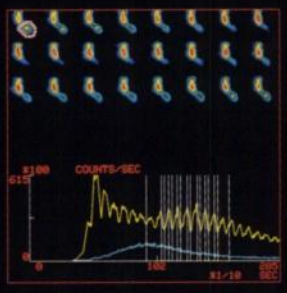
Thallium tomogram report



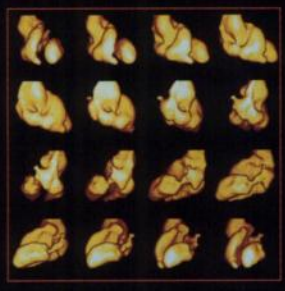
Gated SPECT wall-motion analysis

Segmental wall-motion assessment

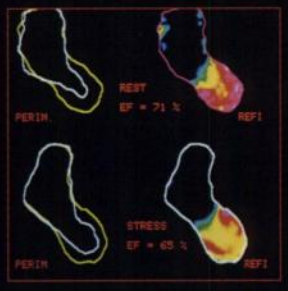
Cedars Sinai quantitative SPECT



First-Pass RNA analysis



Gated SPECT 3D surface-map



First-Pass rest/exercise wall-motion

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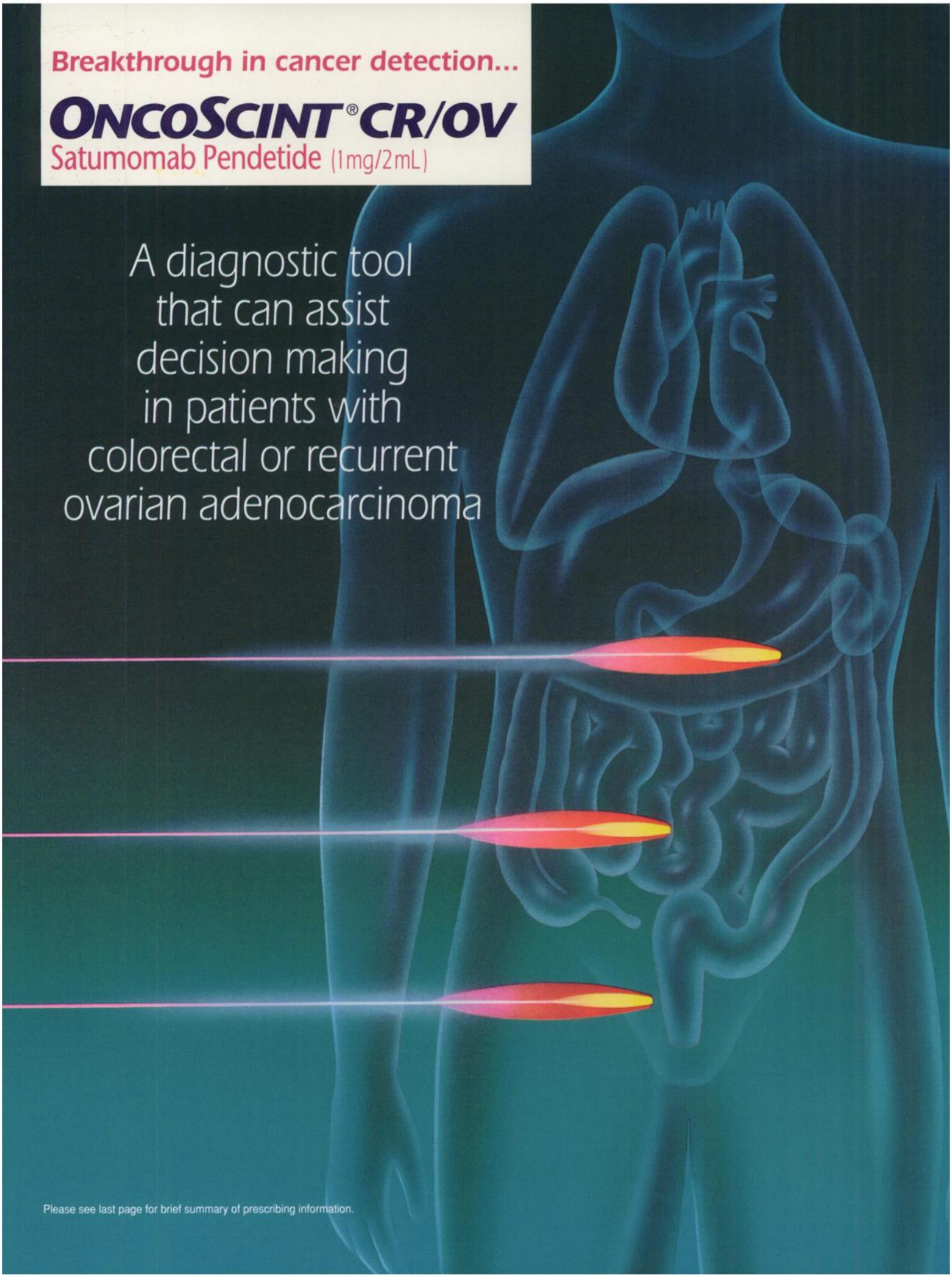
CardiaL is pending U.S. FDA clearance.

Breakthrough in cancer detection...

ONCOSCINT® CR/OV

Satumomab Pendetide (1mg/2mL)

A diagnostic tool that can assist decision making in patients with colorectal or recurrent ovarian adenocarcinoma



Please see last page for brief summary of prescribing information.

ONCOSCINT® CR/OV

Satumomab Pendetide (1mg/2mL)

To enhance decision making in the management of patients with

The first monoclonal antibody-based in determining both the location and

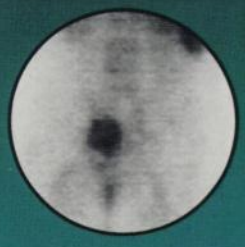
Reveals malignancy with tumor-targeted accuracy—

specifically targets the cell-surface antigen, TAG-72, common to colorectal and ovarian adenocarcinomas,[1,2] making it possible—with the use of existing nuclear medicine equipment—to detect extrahepatic abdominal and pelvic lesions.[3,4]

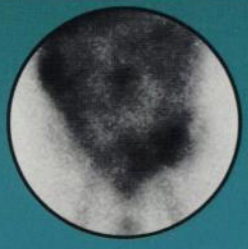
Provides information beyond the scope of standard diagnostic modalities—when interpreted in conjunction with a review of information obtained from other appropriate tests

Found to be beneficial in these difficult situations:

- determining the source of a rising serum tumor marker in patients with an otherwise-negative workup[2,4,5]

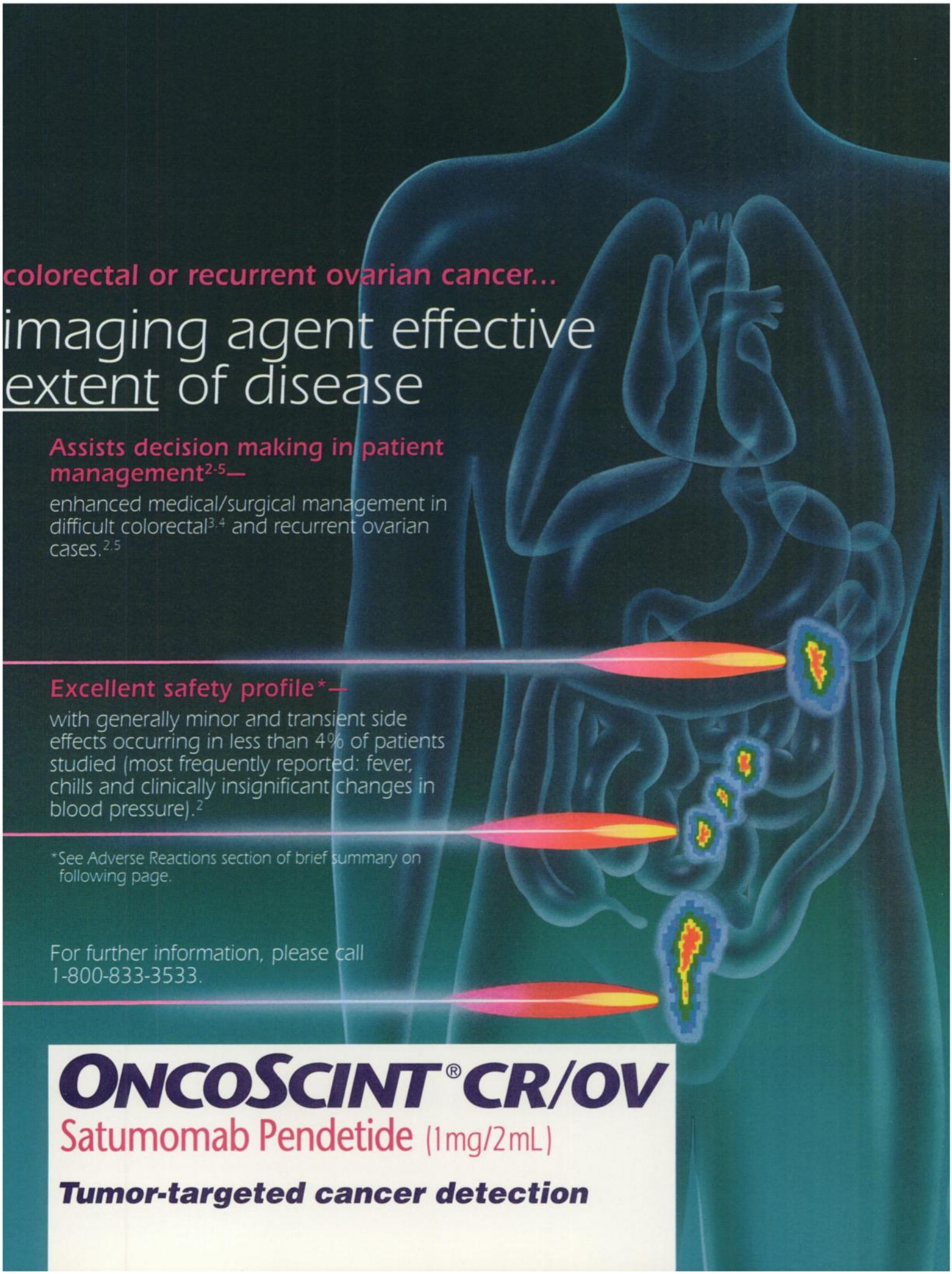


- determining extrahepatic abdominal and pelvic involvement in patients thought to have isolated and resectable recurrence[2,4]



- differentiating disease from postsurgical or postradiation anatomic changes[4]

Please see last page for brief summary of prescribing information.



colorectal or recurrent ovarian cancer...

imaging agent effective extent of disease

Assists decision making in patient management[2-5]—

enhanced medical/surgical management in difficult colorectal[3,4] and recurrent ovarian cases.[2,5]

Excellent safety profile*—

with generally minor and transient side effects occurring in less than 4% of patients studied (most frequently reported: fever, chills and clinically insignificant changes in blood pressure).[2]

*See Adverse Reactions section of brief summary on following page.

For further information, please call 1-800-833-3533.

ONCOSCINT® CR/OV

Satumomab Pendetide (1mg/2mL)

Tumor-targeted cancer detection

OncoScint® CR/OV Kit (satumomab pendetide)

Kit for the Preparation of indium In 111 satumomab pendetide
For Intravenous Use Only
Brief summary of prescribing information

INDICATIONS AND USAGE

OncoScint® CR/OV-In (indium In 111 satumomab pendetide) is a diagnostic imaging agent that is indicated for determining the extent and location of extrahepatic malignant disease in patients with known colorectal or ovarian cancer. Clinical studies suggest that this imaging agent should be used after completion of standard diagnostic tests when additional information regarding disease extent could aid in patient management. The diagnostic images acquired with OncoScint® CR/OV-In should be interpreted in conjunction with a review of information obtained from other appropriate tests.

OncoScint® CR/OV-In is not indicated as a screening test for ovarian or colorectal cancer.

Administration of OncoScint® CR/OV-In may result in falsely elevated values from *in vitro* immunoassays, including tests for carcinoembryonic antigen (CEA) and CA 125. Because this interference may persist for months, the clinical laboratory should investigate for assay interference in patients who develop elevated CEA or CA 125 subsequent to imaging with OncoScint® CR/OV-In (see *Drug/Laboratory Test Interactions*).

Due to insufficient safety and efficacy data regarding repeat administration of this product, this imaging agent is limited to single use only.

CONTRAINDICATIONS

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

WARNINGS

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

PRECAUTIONS

General The components of the kit are sterile and pyrogen free and contain no preservative. OncoScint® CR/OV-In (indium In 111 satumomab pendetide) should be used within 8 hours after radiolabeling. It is essential to follow the directions for preparation carefully and to adhere to strict aseptic procedures during preparation of the radiolabeled product.

Each OncoScint® CR/OV kit is a unit of use package. The contents of the kit are to be used only to prepare OncoScint® CR/OV-In; unlabeled OncoScint® CR/OV should NOT be administered directly to the patient. After radiolabeling with indium-111, the entire OncoScint® CR/OV-In dose must be administered to the patient for whom it was prescribed. **Reducing the dose of either component may adversely impact imaging results, and, therefore, is not recommended.**

The contents of the kit are not radioactive. However, after the indium In 111 chloride is added, appropriate shielding of OncoScint® CR/OV-In must be maintained. Care should be taken to minimize radiation exposure to patients and medical personnel, consistent with proper hospital and patient management procedures.

In addition, radiopharmaceuticals should be used only by physicians and other professionals who are qualified by training and experience in the safe use and handling of radionuclides.

Information for Patients Murine monoclonal antibodies are foreign proteins, and their administration can induce human anti-murine antibodies (HAMA). While limited data exist concerning the clinical significance of HAMA, the presence of HAMA may interfere with murine-antibody based immunoassays, could compromise the efficacy of diagnostic or therapeutic murine antibody-based agents, and may increase the risk of adverse reactions. For these reasons, patients should be informed that the use of this product could affect the future use of other murine-based products, including OncoScint® CR/OV-In, and should be advised to discuss prior use of murine-antibody based products with their physicians (see *Heterologous Protein Administration*).

Heterologous Protein Administration Murine monoclonal antibodies (MAbs) are heterologous proteins, and their administration can induce human anti-murine antibodies (HAMA).

OncoScint® CR/OV-In has been shown to induce HAMA to murine IgG after single administration in about 40% of patients in tumor imaging trials. HAMA levels became negative (undetectable or < 400 ng/mL) in approximately half of such patients at 4 to 12 months after infusion.

While limited data exist concerning the clinical significance of HAMA, detectable HAMA levels can alter the clearance and tissue biodistribution of MAbs. In patients who develop persistently elevated serum HAMA levels, the efficacy of diagnostic or therapeutic murine antibody-based agents may be compromised.

When considering the administration of OncoScint® CR/OV-In to patients who have previously received murine antibody-based products, physicians should be aware of the potential for HAMA to alter clearance and biodistribution. The quality or sensitivity of the imaging study may be compromised. Therefore, prior to administration of murine antibodies, including OncoScint® CR/OV-In, the physician should review the patient history to determine whether the patient has previously received such products.

Preliminary data are available from repeat-administration studies of OncoScint® CR/OV-In in 69 patients who have received 105 repeat doses. However, there are insufficient data to determine the safety and efficacy of this product after repeat administration (see ADVERSE REACTIONS).

Drug/Laboratory Test Interactions: The presence of HAMA in serum may interfere with two-site murine antibody-based immunoassays, including assays for carcinoembryonic antigen (CEA) and CA 125. When present, this interference generally results in falsely high values. If HAMA is known or suspected to be present, the clinical laboratory should be notified and appropriate measures taken to avoid this interference. These methods include the use of non-murine immunoassays, or HAMA removal by adsorption, blocking, or heat inactivation.

Carcinogenesis, Mutagenesis, Impairment of Fertility Long-term animal studies have not been performed to evaluate the carcinogenic or mutagenic potential of OncoScint® CR/OV-In or to evaluate its effect on fertility in males or females.

Pregnancy Category C Animal reproduction studies have not been conducted with OncoScint® CR/OV-In. It is also not known whether OncoScint® CR/OV-In can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. OncoScint® CR/OV-In should not be administered to a pregnant woman unless, in the opinion of the physician, the information to be gained outweighs the potential risks. MAb B72.3 has been shown to react with fetal gastrointestinal tissues.

In general, examinations using radiopharmaceuticals in women of childbearing potential should be performed during the first few days (approximately 10) following the onset of menses.

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

Pediatric Use The safety and effectiveness of OncoScint® CR/OV-In in children have not been established.

ADVERSE REACTIONS

After administration of over 500 single i.v. doses of OncoScint® CR/OV-In (indium In 111 satumomab pendetide) in clinical trials, adverse reactions were observed in less than 4% of patients. No deaths attributable to OncoScint® CR/OV-In administration were reported. The most common adverse reaction was fever, which occurred in less than 2% of patients. Other adverse reactions, each of which occurred in less than 1% of patients, are listed in order of decreasing frequency: chills, hypotension, hypertension, rash, pruritus, sweating, nausea, arthralgia, asthenia, chest pain, headache, hypothermia, pain, flushing, diarrhea, confusion, dizziness, nervousness, crying, and angioedema. Although causality was not determined, an isolated occurrence of reversible thrombocytopenia was observed in a patient who received OncoScint® CR/OV-In in clinical trials.

Additional adverse reactions after 105 repeat administrations of OncoScint® CR/OV-In in 69 patients included two reports of fever, one complaint of abdominal pain, and two cases of non-serious, readily reversible reactions characterized primarily by flank pain.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

The dose of OncoScint® CR/OV (satumomab pendetide) is 1 mg radiolabeled with 5 mCi of indium In 111 chloride. Each dose is administered intravenously over 5 minutes and should not be mixed with any other medication during its administration. The patient dose of the radiolabel should be measured in a dose calibrator prior to administration.

Each OncoScint® CR/OV kit is a unit dose package. After radiolabeling with indium-111, the entire OncoScint® CR/OV-In dose should be administered to the patients. **Reducing the dose of either component may adversely impact imaging results, and is, therefore, not recommended.**

HOW SUPPLIED

The OncoScint® CR/OV kit (NDC No. 0044-0579-01) for the preparation of indium-111 labeled OncoScint® CR/OV includes one vial containing 1 mg of satumomab pendetide per 2 mL of sodium phosphate buffered saline and one 2 mL vial of sodium acetate buffer solution, 0.5 *M*. These solutions are sterile and pyrogen free and contain no preservative. Each kit also includes one sterile 0.22 µm Millex® GV filter, prescribing information, and two identification labels.

U.S. Patent Nos. 4,671,958 and 4,741,900

Revised 12/30/92

References **1.** Nabi HA, Doerr RJ. Radiolabeled monoclonal antibody imaging (immunoscintigraphy) of colorectal cancers: current status and future perspectives. *Am J Surg.* 1992;163:448-456. **2.** Data on file. Cytogen Corporation, Princeton, NJ. **3.** Doerr RJ, Abdel-Nabi H, Krag D, et al. Radiolabeled antibody imaging in the management of colorectal cancer: results of a multicenter clinical study. *Ann Surg.* 1991;118-124.**4.** Collier BD, Abdel-Nabi H, Doerr RJ, et al. Immunoscintigraphy with ^{111}In-CYT-103 in the management of colorectal carcinoma: a comparison with computed tomography. *Radiology.* 1992;185:179-186. **5.** Surwit EA, Childers JM, Krag DN, et al. Clinical assessment of ^{111}In-CYT-103 immunoscintigraphy in ovarian cancer. *Gynecol Oncol.* 1993; 48:285-292.

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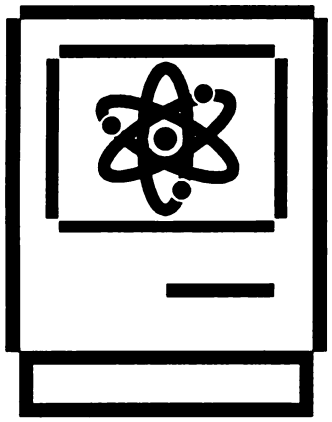

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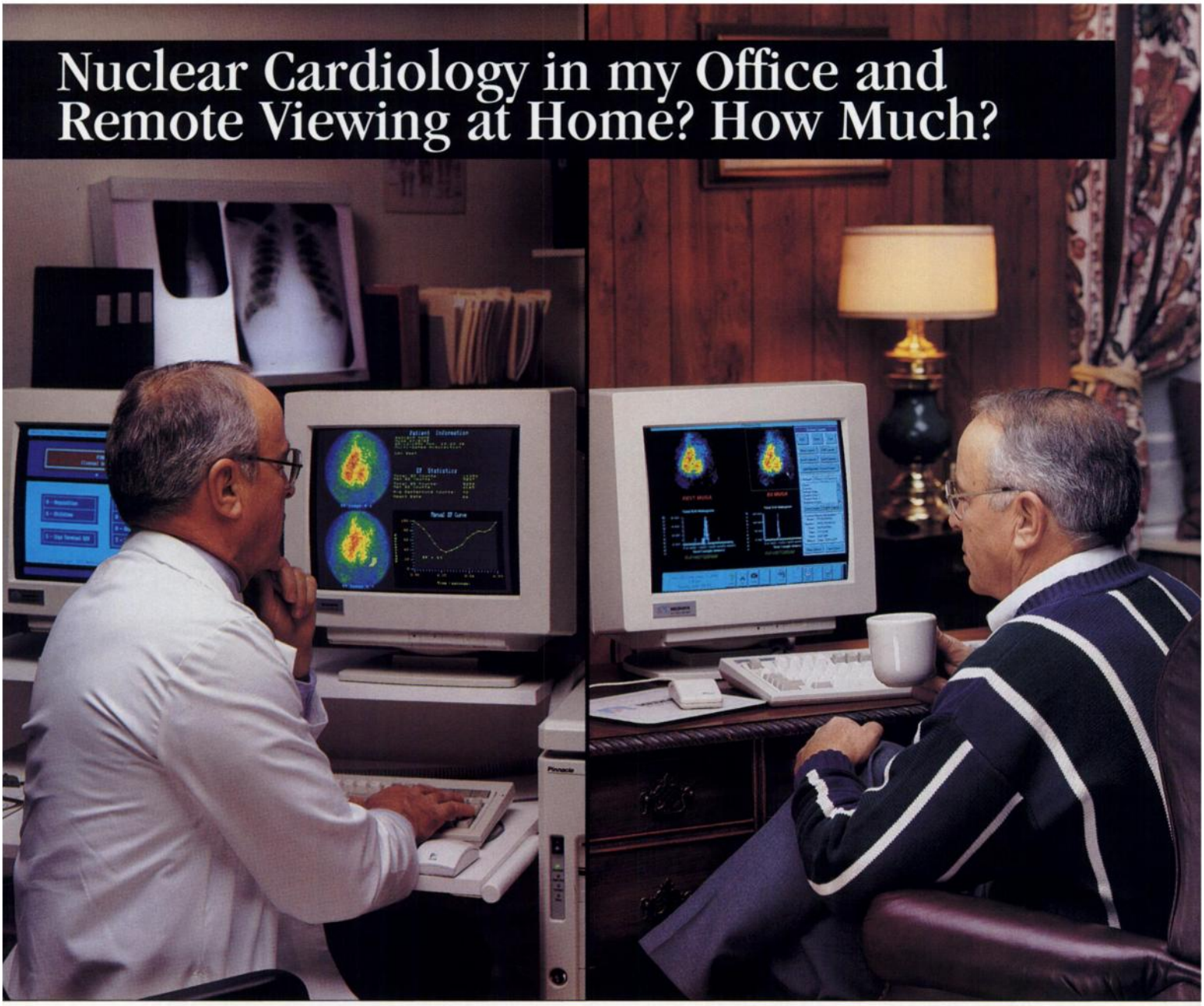

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All the major manufacturers of nuclear medicine products and services more than 100 in all-will be on hand to explain and demonstrate the most technologically-advanced equipment. Several companies will present User Meetings to give an in-depth understanding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

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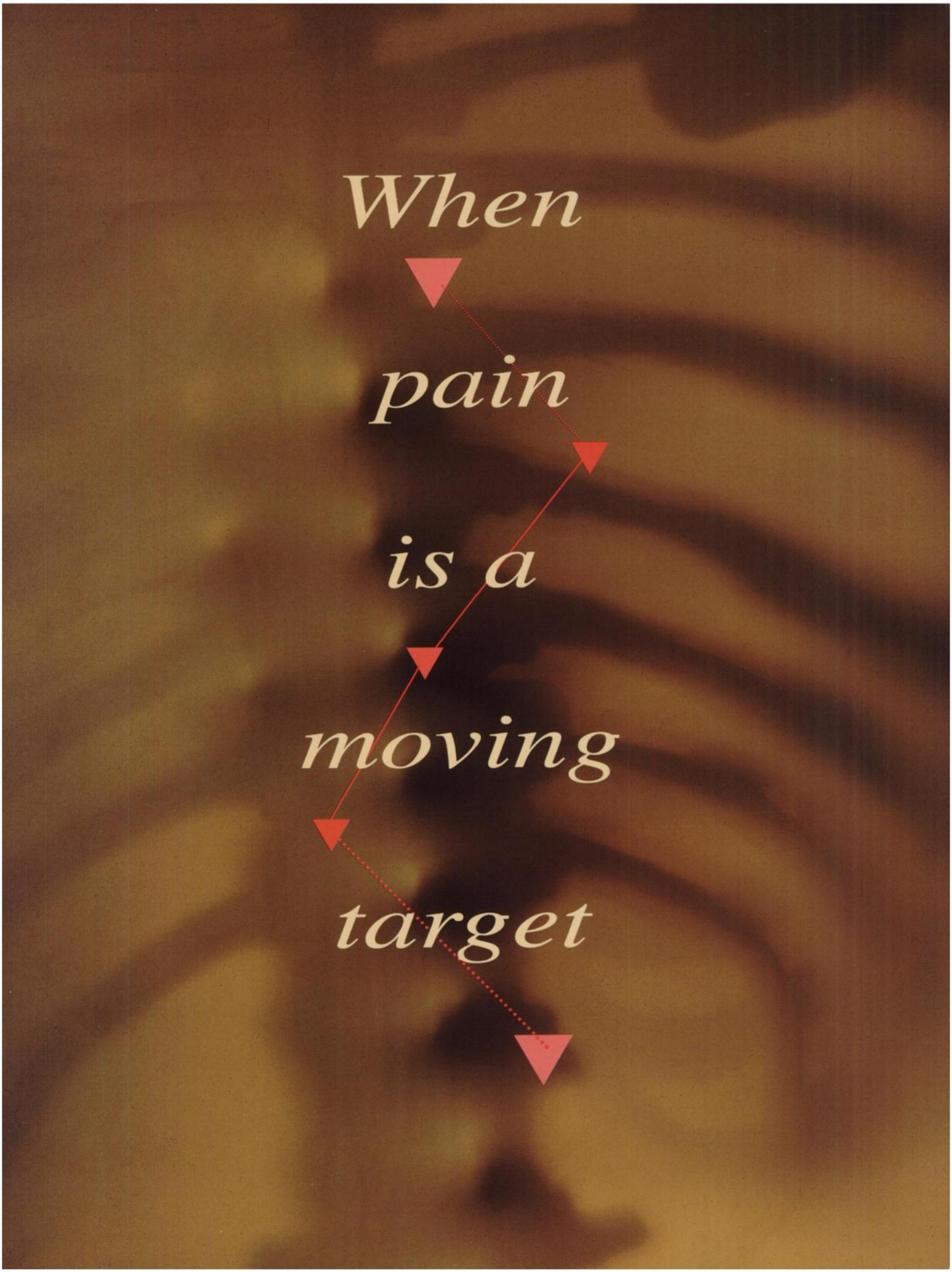
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is a
moving
target

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Simultaneously targets all sites of metastatic bone pain.

LONG-TERM PALLIATION IN ONE CONVENIENT DOSE.

- Palliation of pain demonstrated in the majority of patients.[1,2]
- One dose of Metastron provides pain relief for an average of up to 6 months.[1]
- As an adjunct to radiotherapy, 63.6% of patients receiving Metastron (10.8 mCi) had reduced pain at 6 months as compared to 35.0% of patients receiving placebo (n=42).[3]
- Preferentially incorporates into multiple sites of metastatic bone — the dose absorbed in metastatic deposits is approximately ten times that absorbed in normal bone marrow.[4,5]

ADJUNCTIVELY DELAYS THE MEDIAN TIME TO PROGRESSION OF PAIN BY 28.1 WEEKS OVER RADIOTHERAPY ALONE.

Median time to requirement for additional radiotherapy at new pain site.[3]

From a multicenter, double-blind study of 126 patients who received a single injection of either Metastron 400 MBq, 10.8 mCi or placebo with fractionated doses of local field radiotherapy (20-30 Gy).

HIGHLY EFFECTIVE NON-NARCOTIC THERAPY.

- Metastron may reduce or eliminate the need for dose escalation of narcotic analgesics.[1,3]
- Onset of pain relief is generally within 7 to 20 days — Metastron is therefore not recommended in patients with very short life expectancy.

GENERALLY WELL TOLERATED.

- A depression of white blood cell (20%) and platelet (30%) levels may occur in patients treated with Metastron — clinically significant toxicity is rare.
- Metastron should be used with caution in patients with significantly compromised bone marrow from previous treatment. Caution should also be used in patients with platelet counts below 60,000 or white blood cell counts below 2,400.
- Some patients have reported a transient increase in bone pain lasting 36 to 72 hours following an injection — this can usually be controlled with analgesics.

AN IMPROVED QUALITY OF LIFE FOR PATIENTS.

- Metastron may improve patient quality of life, as measured by assessments of mood, mobility, appetite, sleep pattern, and analgesic consumption.[1-4]

Please see following page for full prescribing information.

METASTRON®

(STRONTIUM-89 CHLORIDE INJECTION)

An effective way to manage metastatic bone pain.

METASTRON®
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An effective way to manage metastatic bone pain.

Consult your radiation safety officer for product availability or call Amersham Healthcare/ Medi-Physics Technical Services at 1-800-554-0157.

Metastron® (Strontium-89 Chloride Injection)

Description: Metastron is a sterile, non-pyrogenic, aqueous solution of Strontium-89 Chloride for intravenous administration. The solution contains no preservative.

Each milliliter contains:	Strontium Chloride	10.9 - 22.6 mg
	Water for Injection	q.s. to 1 mL

The radioactive concentration is 37 MBq/mL, 1 mCi/mL and the specific activity is 2.96 - 6.17 MBq/mg, 80-167 µCi/mg at calibration. The pH of the solution is 4 - 7.5.

Physical Characteristics: Strontium-89 decays by beta emission with a physical half-life of 50.5 days. The maximum beta energy is 1.463 MeV (100%). The maximum range of ß- from Strontium-89 in tissue is approximately 8 mm.

Radioactive decay factors to be applied to the stated value for radioactive concentration at calibration, when calculating injection volumes at the time of administration, are given in Table 1.

Table 1: Decay of Strontium-89

Day*	Factor	Day*	Factor	Day*	Factor	Day*	Factor
-24	1.39	-12	1.18	+6	0.92	+18	0.78
-22	1.35	-10	1.15	+8	0.90	+20	0.76
-20	1.32	-8	1.12	+10	0.87	+22	0.74
-18	1.28	-6	1.09	+12	0.85	+24	0.72
-16	1.25	-4	1.06	+14	0.83	+26	0.70
-14	1.21	-2	1.03	+16	0.80	+28	0.68
		0 = calibration	1.00				

*Days before (-) or after (+) the calibration date stated on the vial.

Clinical Pharmacology: Following intravenous injection, soluble strontium compounds behave like their calcium analogs, clearing rapidly from the blood and selectively localizing in bone mineral. Uptake of strontium by bone occurs preferentially in sites of active osteogenesis; thus primary bone tumors and areas of metastatic involvement (blastic lesions) can accumulate significantly greater concentrations of strontium than surrounding normal bone.

Strontium-89 Chloride is retained in metastatic bone lesions much longer than in normal bone, where turnover is about 14 days. In patients with extensive skeletal metastases, well over half of the injected dose is retained in the bones.

Excretion pathways are two-thirds urinary and one-third fecal in patients with bone metastases. Urinary excretion is higher in people without bone lesions. Urinary excretion is greatest in the first two days following injection.

Strontium-89 is a pure beta emitter and Strontium-89 Chloride selectively irradiates sites of primary and metastatic bone involvement with minimal irradiation of soft tissues distant from the bone lesions. (The maximum range in tissue is 8 mm; maximum energy is 1.463 MeV.) Mean absorbed radiation doses are listed under the **Radiation Dosimetry** section.

Clinical trials have examined relief of pain in cancer patients who have received therapy for bone metastases (external radiation to indexed sites) but in whom persistent pain recurred. In a multi-center Canadian placebo-controlled trial of 126 patients, pain relief occurred in more patients treated with a single injection of Metastron than in patients treated with an injection of placebo. Results are given in the following tables.

Table 2 compares the percentage and number of patients treated with Metastron or placebo who had reduced pain and no increase in analgesic or radiotherapy re-treatment.

Table 2: Comparison of the effects of Strontium-89 and placebo, as adjunct to radiotherapy, on treatment outcome over time.

	Months Post-Treatment					
	1	2	3	4	5	6
Metastron	71.4% (n=42)	78.9% (n=38)	60.6% (n=33)	59.3% (n=27)	36.4% (n=22)	63.6% (n=22)
Placebo	61.4% (n=44)	57.1% (n=35)	55.9% (n=34)	25.0% (n=24)	31.8% (n=22)	35.0% (n=20)

At each visit, treatment success, defined as a reduction in a patient's pain score without any increase in analgesic intake and without any supplementary radiotherapy at the index site, was more frequent among patients assigned to Metastron than to placebo.

Table 3 compares the number and percentage of patients treated with Metastron or placebo as an adjunct to radiotherapy who were pain free without analgesic at the intervals shown.

Table 3: Comparison of the effects of Strontium-89 and placebo, as adjunct to radiotherapy, on reduction of pain score and analgesic score to zero.

	Months Post-Treatment						
	1	2	3	4	5	6	9
Metastron	6	5	5	3	4	4	2
	14.3% (n=42)	13.2% (n=38)	15.2% (n=33)	11.1% (n=27)	18.2% (n=22)	18.2% (n=22)	18.2% (n=11)
Placebo	3	3	2	0	1	1	0
	6.8% (n=44)	8.6% (n=35)	5.9% (n=34)	(n=24)	4.5% (n=22)	5% (n=20)	(n=17)

The number of patients classified at each visit as treatment successes who were pain free at the index site *and* required no analgesics was consistently higher in the Metastron group.

New pain sites were less frequent in patients treated with Metastron.

In another clinical trial, pain relief was greater in a group of patients treated with Metastron compared with a group treated with non-radioactive strontium-88.

Indications and Usage: Metastron (Strontium-89 Chloride Injection) is indicated for the relief of bone pain in patients with painful skeletal metastases.

The presence of bone metastases should be confirmed prior to therapy.

Contraindications: None known.

Warnings: Use of Metastron in patients with evidence of seriously compromised bone marrow from previous therapy or disease infiltration is not recommended unless the potential benefit of the treatment outweighs its risks. Bone marrow toxicity is to be expected following the administration of Metastron, particularly white blood cells and platelets. The extent of toxicity is variable. It is recommended that the patient's peripheral blood cell counts be monitored at least once every other week. Typically, platelets will be depressed by about 30% compared to pre-administration levels. The nadir of platelet depression in most patients is found between 12 and 16 weeks following administration of Metastron. White blood cells are usually depressed to a varying extent compared to pre-administration levels. Thereafter, recovery occurs slowly, typically reaching pre-administration levels six months after treatment unless the patient's disease or additional therapy intervenes.

In considering repeat administration of Metastron, the patient's hematologic response to the initial dose, current platelet level and other evidence of marrow depletion should be carefully evaluated.

Verification of dose and patient identification is necessary prior to administration because Metastron delivers a relatively high dose of radioactivity.

Metastron may cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

Precautions: Metastron is not indicated for use in patients with cancer not involving bone. Metastron should be used with caution in patients with platelet counts below 60,000 and white cell counts below 2,400.

Radiopharmaceuticals should only be used 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.

Metastron, like other radioactive drugs, must be handled with care and appropriate safety measures taken to minimize radiation to clinical personnel.

In view of the delayed onset of pain relief, typically 7 to 20 days post injection, administration of Metastron to patients with very short life expectancy is not recommended.

A calcium-like flushing sensation has been observed in patients following a rapid (less than 30-second injection) administration.

Special precautions, such as urinary catheterization, should be taken following administration to patients who are incontinent to minimize the risk of radioactive contamination of clothing, bed linen and the patient's environment.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Data from a repetitive dose animal study suggests that Strontium-89 Chloride is a potential carcinogen. Thirty-three of 40 rats injected with Strontium-89 Chloride in ten consecutive monthly doses of either 250 or 350 µCi/kg developed malignant bone tumors after a latency period of approximately 9 months. No neoplasia was observed in the control animals. Treatment with Strontium-89 Chloride should be restricted to patients with well documented metastatic bone disease.

Adequate studies with Strontium-89 Chloride have not been performed to evaluate mutagenic potential or effects on fertility.

Pregnancy: Teratogenic effects.

Pregnancy Category D. See **Warnings** section.

Nursing Mothers: Because Strontium acts as a calcium analog, secretion of Strontium-89 Chloride into human milk is likely. It is recommended that nursing be discontinued by mothers about to receive intravenous Strontium-89 Chloride. It is not known whether this drug is excreted in human milk.

Pediatric Use: Safety and effectiveness in children below the age of 18 years have not been established.

Adverse Reactions: A single case of fatal septicemia following leukopenia was reported during clinical trials. Most severe reactions of marrow toxicity can be managed by conventional means.

A small number of patients have reported a transient increase in bone pain at 36 to 72 hours after injection. This is usually mild and self-limiting, and controllable with analgesics. A single patient reported chills and fever 12 hours after injection without long-term sequelae.

Dosage and Administration: The recommended dose of Metastron is 148 MBq, 4 mCi, administered by slow intravenous injection (1-2 minutes). Alternatively, a dose of 1.5 - 2.2 MBq/kg, 40-60 µCi/kg body weight may be used.

Repeated administrations of Metastron should be based on an individual patient's response to therapy, current symptoms, and hematologic status, and are generally not recommended at intervals of less than 90 days.

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

Radiation Dosimetry: The estimated radiation dose that would be delivered over time by the intravenous injection of 37 MBq, 1 mCi of Strontium-89 to a normal healthy adult is given in Table 4. Data are taken from the ICRP publication "Radiation Dose to Patients from Radiopharmaceuticals"-ICRP #53, Vol. 18 No. 1-4, Page 171, Pergamon Press, 1988.

Table 4: Strontium-89 Dosimetry

Organ	mGy/MBq	rad/mCi	Organ	mGy/MBq	rad/mCi
Bone Surface	17.0	63.0	Testes	0.8	2.9
Red Bone Marrow	11.0	40.7	Ovaries	0.8	2.9
Lower Bowel Wall	4.7	17.4	Uterine Wall	0.8	2.9
Bladder Wall	1.3	4.8	Kidneys	0.8	2.9

When blastic osseous metastases are present, significantly enhanced localization of the radiopharmaceutical will occur with correspondingly higher doses to the metastases compared with normal bones and other organs.

The radiation dose hazard in handling Strontium-89 Chloride injection during dose dispensing and administration is similar to that from phosphorus-32. The beta emission has a range in water of about 8 mm (max.) and in glass of about 3 mm, but the bremsstrahlung radiation may augment the contact dose.

Measured values of the dose on the surface of the unshielded vial are about 65 mR/minute/mCi.

It is recommended that the vial be kept inside its transportation shield whenever possible.

How Supplied: Metastron is supplied in a 10 mL vial containing 148 MBq, 4 mCi. The vial is shipped in a transportation shield with approximately 3 mm lead wall thickness, package insert, and two therapeutic agent warning labels.

The vial and its contents should be stored inside its transportation container at room temperature (15-25° C, 59-77° F).

The calibration date (for radioactivity content) and expiration date are quoted on the vial label. The expiration date will be 28 days after calibration. Stability studies have shown no change in any of the product characteristics monitored during routine product quality control over the period from manufacture to expiration.

This radiopharmaceutical is licensed by the Illinois Department of Nuclear Safety for distribution to persons licensed pursuant to 32 Illinois Adm. Code 330.260 (a) and Part 335 Subpart F.335.5010 or under equivalent licenses of the USNRC or an Agreement State.

THIS PRODUCT INFORMATION ISSUED JUNE, 1993. Product Code: SMS.2PA

Manufactured by: **Amersham International plc**, Amersham, England

Medi-Physics, Inc., 2636 S. Clearbrook Drive, Arlington Heights, Illinois 60005

References:

1. Data on file, Amersham International plc, Amersham, England. 2. Lewington VJ, McEwan AJ, Ackery DM, et al. A prospective, randomised double-blind crossover study to examine the efficacy of strontium-89 in pain palliation in patients with advanced prostate cancer metastatic to bone. *Eur J Cancer*. 1991;27:954-958. 3. Porter AT, McEwan AJB, Powe JE, et al. Results of a randomized phase-III trial to evaluate the efficacy of strontium-89 adjuvant to local field external beam irradiation in the management of endocrine resistant metastatic prostate cancer. *Int J Radiat Oncol Biol Phys*. 1993;25:805-813. 4. Blake GM, Zivanovic MA, McEwan AJ, et al. "Sr radionuclide therapy: dosimetry and haematological toxicity in two patients with metastasising prostatic carcinoma. *Eur J Nucl Med*. 1987;13:41-46. 5. Blake GM, Zivanovic MA, McEwan AJ, et al. Sr-89 therapy: strontium kinetics in disseminated carcinoma of the prostate. *Eur J Nucl Med*. 1986;12:447-454.

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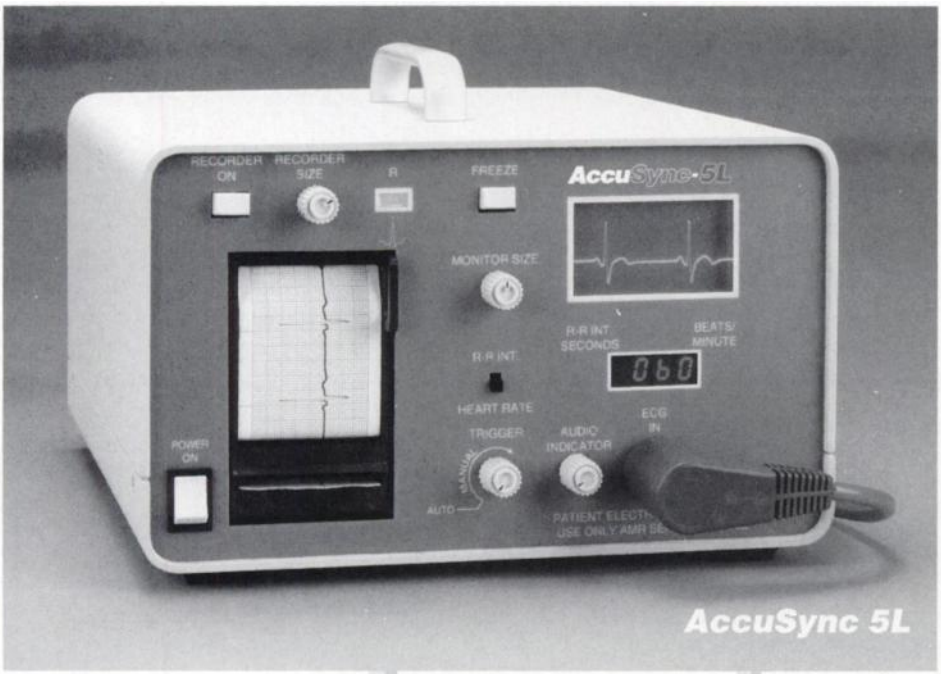

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- No delay
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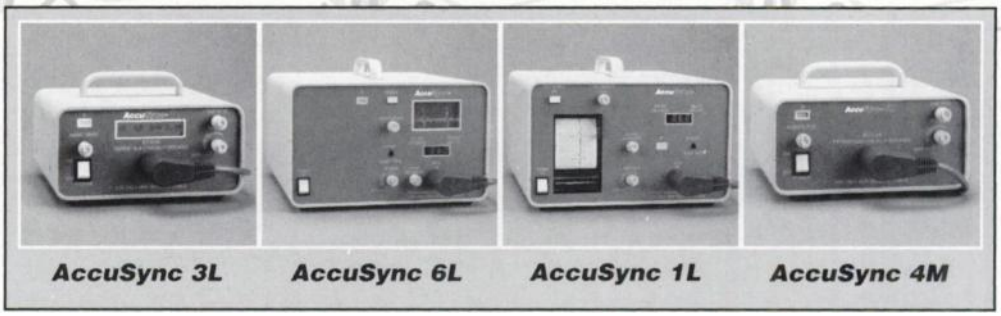
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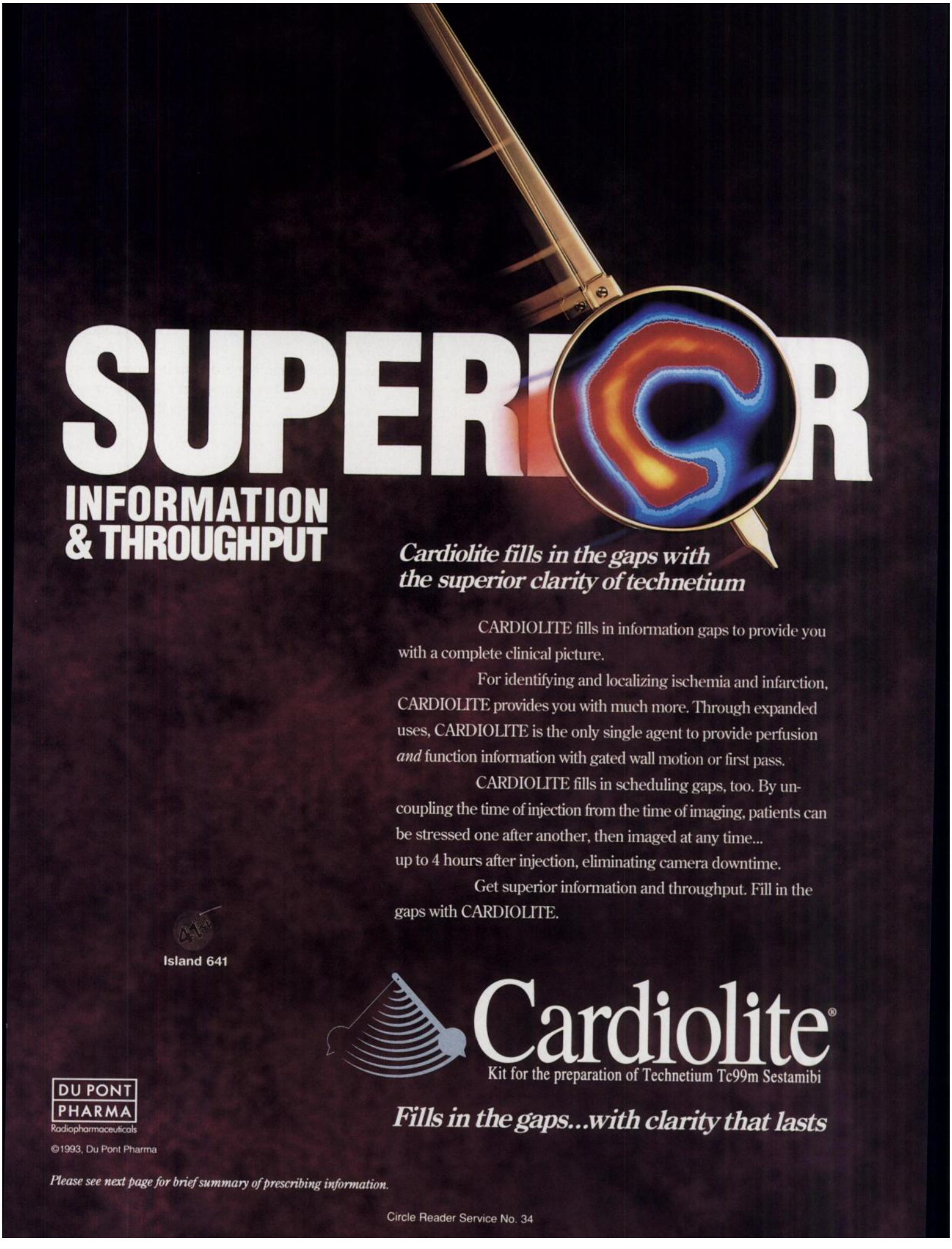

Brief Summary

Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

FOR DIAGNOSTIC USE

DESCRIPTION: Each 5ml vial contains a sterile, non-pyrogenic, lyophilized mixture of:

Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate - 1.0mg
Sodium Citrate Dihydrate - 2.6mg
L-Cysteine Hydrochloride Monohydrate - 1.0mg
Mannitol - 20mg
Stannous Chloride, Dihydrate, minimum ($SnCl_2 \cdot 2H_2O$) - 0.025mg
Stannous Chloride, Dihydrate, ($SnCl_2 \cdot 2H_2O$) - 0.075mg
Tin Chloride (Stannous and Stannic) Dihydrate, maximum (as $SnCl_2 \cdot 2H_2O$) - 0.086mg

Prior to lyophilization the pH is 5.3-5.9. The contents of the vial are lyophilized and stored under nitrogen.

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxidant-free Sodium Pertechnetate Tc99m Injection.The pH of the reconstituted product is 5.5 (5.0-6.0). No bacteriostatic preservative is present.

The precise structure of the technetium complex is $Tc99m[MIBI]_6^+$ where MIBI is 2-methoxy isobutyl isonitrile.

INDICATIONS AND USAGE: CARDIOLITE, Kit for the preparation of Technetium Tc99m Sestamibi is a myocardial perfusion agent that is useful in the evaluation of ischemic heart disease. CARDIOLITE, Kit for the preparation of Technetium Tc99m Sestamibi is useful in distinguishing normal from abnormal myocardium and in the localization of the abnormality, in patients with suspected myocardial infarction, ischemic heart disease or coronary artery disease. Evaluation of ischemic heart disease or coronary artery disease is accomplished using rest and stress techniques.

CARDIOLITE, Kit for the preparation of Technetium Tc99m Sestamibi, is also useful in the evaluation of myocardial function using the first pass technique.

Rest-exercise imaging with Tc99m Sestamibi in conjunction with other diagnostic information may be used to evaluate ischemic heart disease and its localization.

In clinical trials, using a template consisting of the anterior wall, inferior-posterior wall and isolated apex, localization in the anterior or inferior-posterior wall in patients with suspected angina pectoris or coronary artery disease was shown. Disease localization isolated to the apex has not been established. Tc99m Sestamibi has not been studied or evaluated in other cardiac diseases.

It is usually not possible to differentiate recent from old myocardial infarction or to differentiate 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).

PRECAUTIONS:

GENERAL

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

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

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

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

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

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

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

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

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

The active intermediate, $[Cu(MIBI)_4]BF_4$, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all *in vitro*). At cytotoxic concentrations (≥ 20μg/ml), an increase in cells with chromosome aberrations was observed in the *in vitro* human lymphocyte assay. $[Cu(MIBI)_4]BF_4$ did not show genotoxic effects in the *in vivo* mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9mg/kg, > 600 × maximal human dose).

Pregnancy Category C

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

Nursing Mothers

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

Pediatric Use

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

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient metallic or bitter taste immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing and non-itching rash have also 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 the 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.

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

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

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

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

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

	Estimated Radiation Absorbed Dose			
	REST			
	2.0 hour void		4.8 hour void	
Organ	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.9
Gallbladder Wall	2.0	20.0	2.0	20.0
Small Intestine	3.0	30.0	3.0	30.0
Upper Large Intestine Wall	5.4	55.5	5.4	55.5
Lower Large Intestine Wall	3.9	40.0	4.2	41.1
Stomach Wall	0.6	6.1	0.6	5.8
Heart Wall	0.5	5.1	0.5	4.9
Kidneys	2.0	20.0	2.0	20.0
Liver	0.6	5.8	0.6	5.7
Lungs	0.3	2.8	0.3	2.7
Bone Surfaces	0.7	6.8	0.7	6.4
Thyroid	0.7	7.0	0.7	6.8
Ovaries	1.5	15.5	1.6	15.5
Testes	0.3	3.4	0.4	3.9
Red Marrow	0.5	5.1	0.5	5.0
Urinary Bladder Wall	2.0	20.0	4.2	41.1
Total Body	0.5	4.8	0.5	4.8
	STRESS			
	2.0 hour void		4.8 hour void	
Organ	rads/ 30mCi	mGy/ 1110MBq	rads/ 30mCi	mGy/ 1110MBq
Breasts	0.2	2.0	0.2	1.8
Gallbladder Wall	2.8	28.9	2.8	27.8
Small Intestine	2.4	24.4	2.4	24.4
Upper Large Intestine Wall	4.5	44.4	4.5	44.4
Lower Large Intestine Wall	3.3	32.2	3.3	32.2
Stomach Wall	0.5	5.3	0.5	5.2
Heart Wall	0.5	5.6	0.5	5.3
Kidneys	1.7	16.7	1.7	16.7
Liver	0.4	4.2	0.4	4.1
Lungs	0.3	2.6	0.2	2.4
Bone Surfaces	0.6	6.2	0.6	6.0
Thyroid	0.3	2.7	0.2	2.4
Ovaries	1.2	12.2	1.3	13.3
Testes	0.3	3.1	0.3	3.4
Red Marrow	0.5	4.6	0.5	4.4
Urinary Bladder Wall	1.5	15.5	3.0	30.0
Total Body	0.4	4.2	0.4	4.2

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

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

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

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

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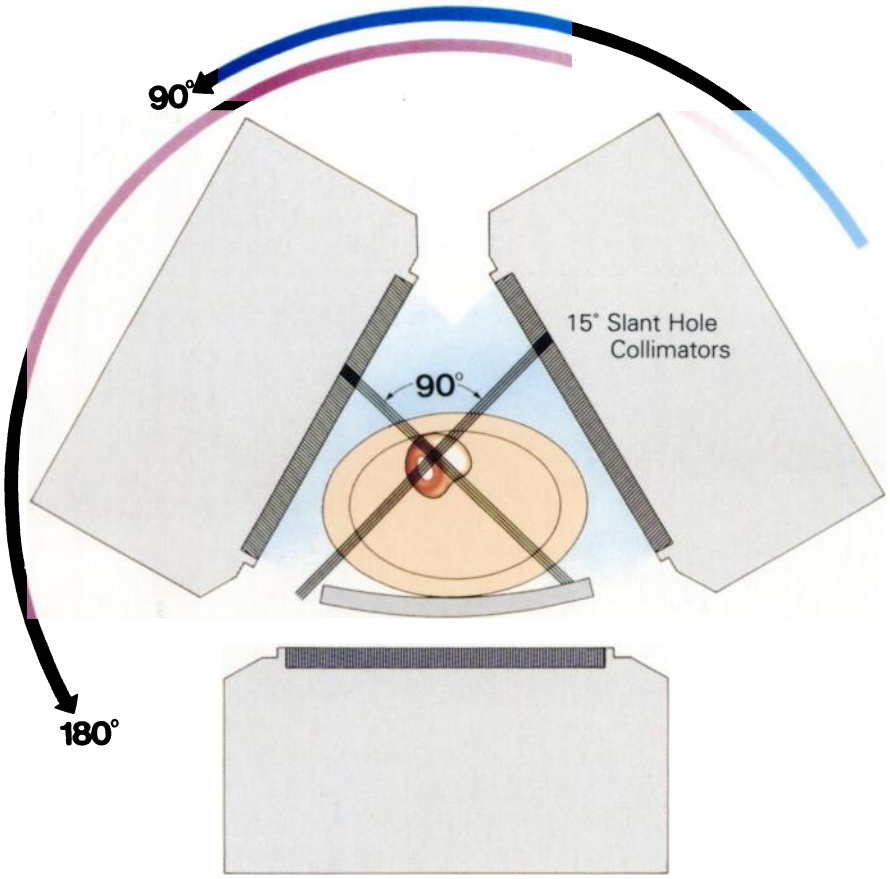

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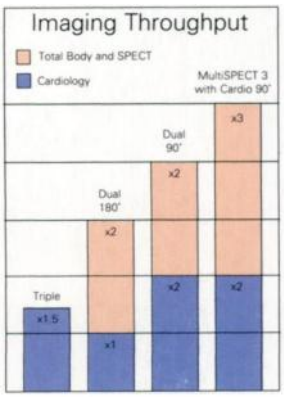

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