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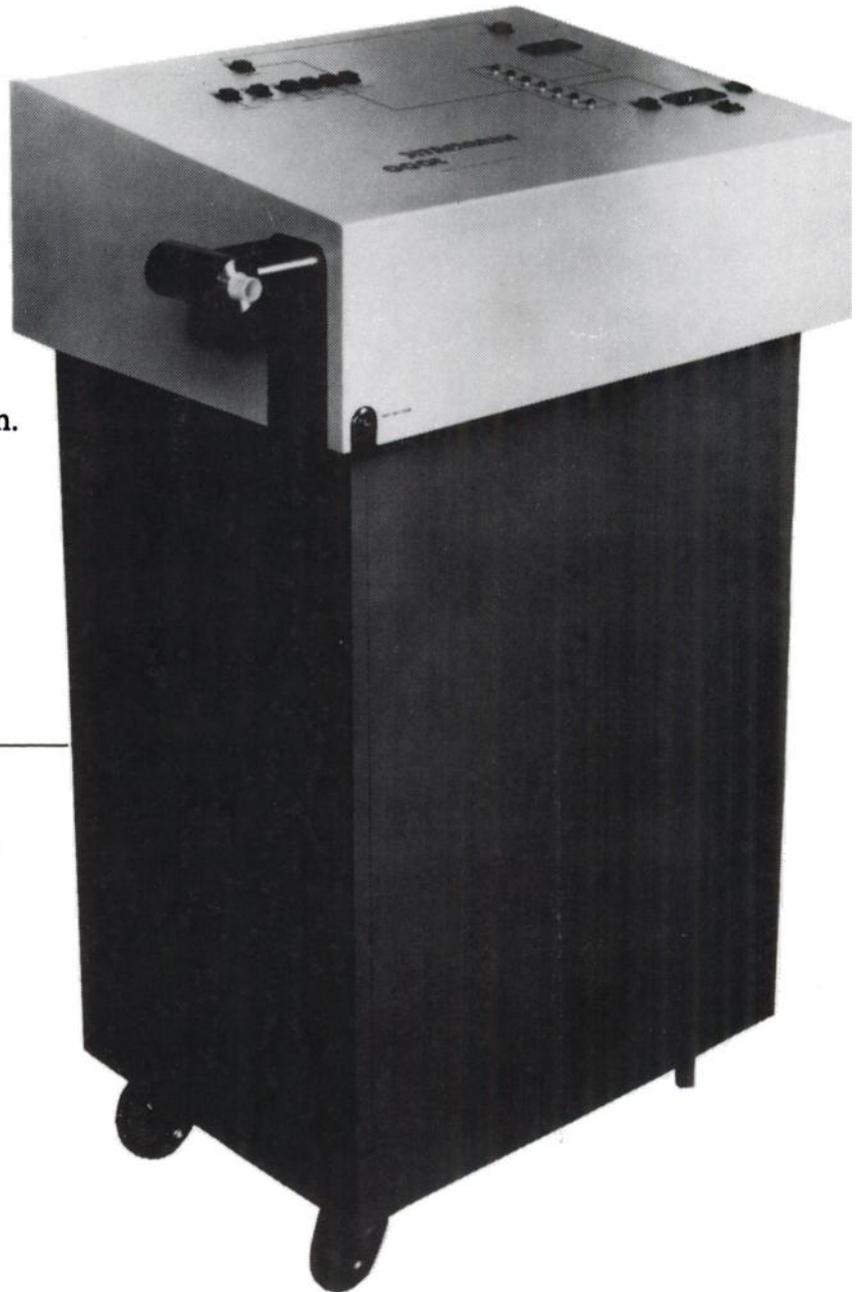
If you are considering a new nuclear medicine imaging system, plug into the high energy of *SMV*. For more information on our dynamic new company, products and services, please contact:

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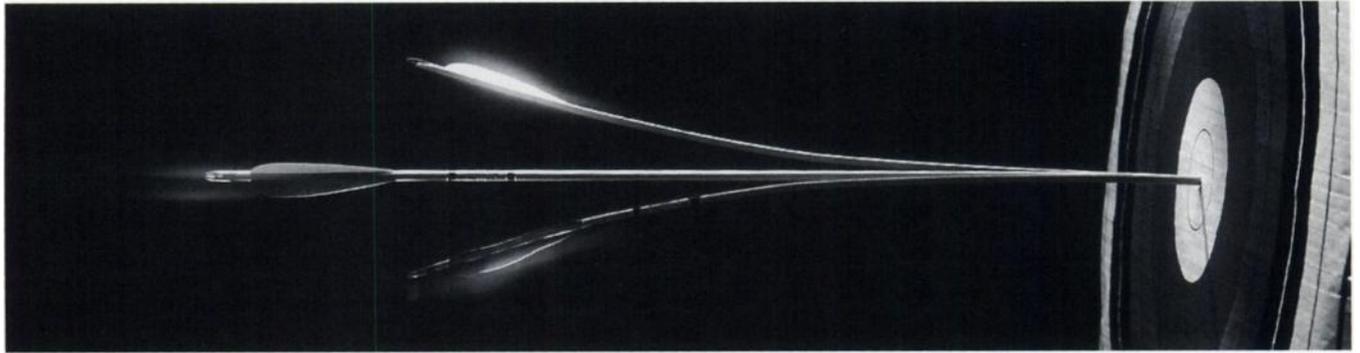
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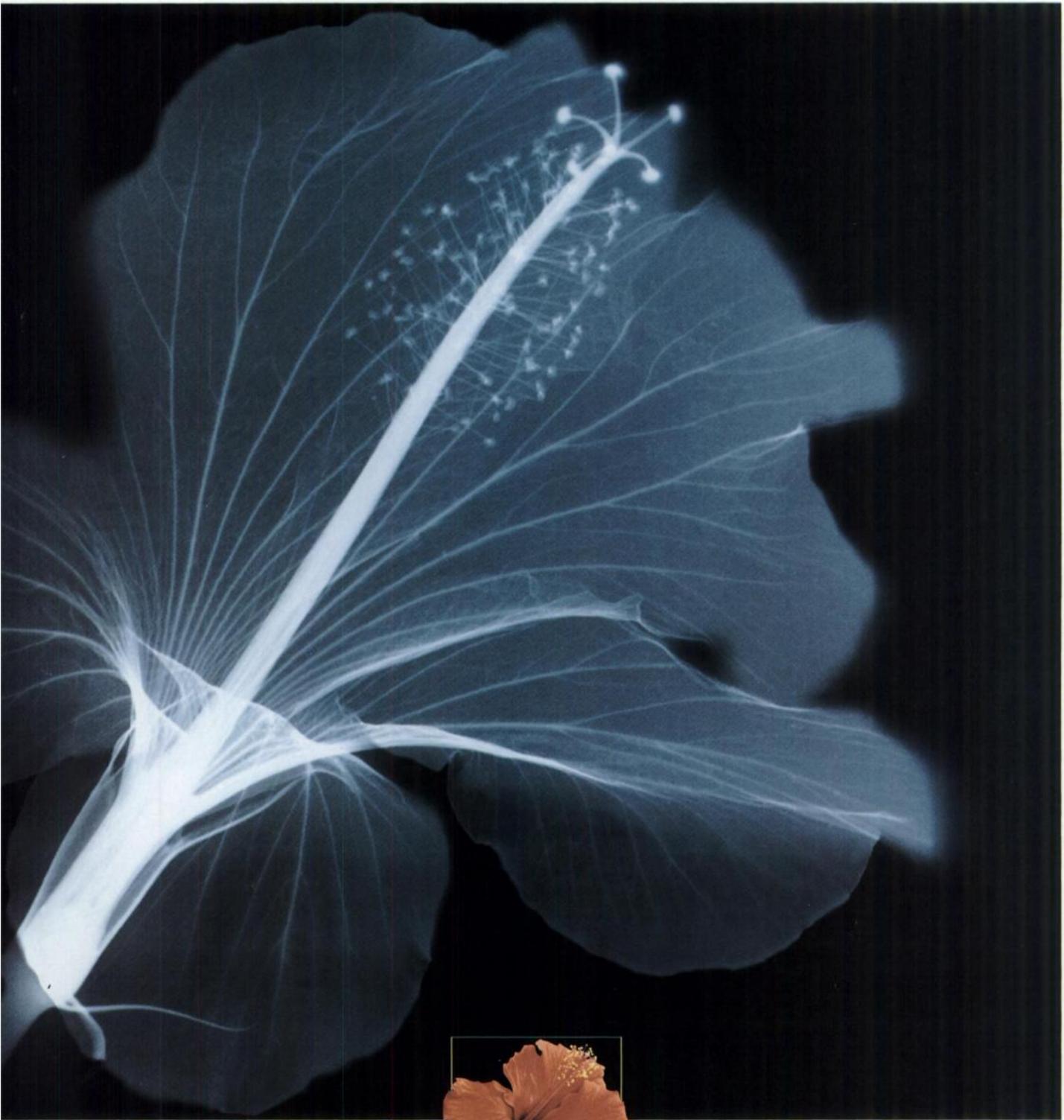
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Cardiolite®

Kit for the preparation of Technetium Tc99m Sestamibi

*To reduce soft-tissue attenuation
Cardiolite comes through*



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.

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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 (SnCl₂·2H₂O) - 0.025mg
 Stannous Chloride, Dihydrate, (SnCl₂·2H₂O) - 0.075mg
 Tin Chloride (Stannous and Stannic) Dihydrate, maximum (as SnCl₂·2H₂O) - 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 Perchnetate 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 Perchnetate 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 Perchnetate 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)₆]BF₄ 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)₆]BF₄ 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 Perchnetate 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 paraesthesia and/or taste perversion (metallic or bitter taste) immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing, edema, injection site inflammation, dyspepsia, nausea, vomiting, pruritus, rash, urticaria, dry mouth, fever, dizziness, fatigue, dyspnea, and hypotension also have been attributed to administration of the agent. Cases of angina, chest pain, and death have occurred (see Warnings and Precautions). The following adverse reactions have been rarely reported: signs and symptoms consistent with seizure occurring shortly after administration of the agent; transient arthritis in a wrist joint; and severe hypersensitivity, which was characterized by dyspnea, hypotension, bradycardia, asthenia and vomiting within two hours after a second injection of Technetium Tc99m Sestamibi.

DOSAGE AND ADMINISTRATION: The suggested dose range for I.V. administration in a single dose to be employed in the average patient (70kg) is:
 370-1110MBq (10-30mCi)

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

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration.

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		4.8 hour void	
	2.0 hour void	4.8 hour void	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 Radiopharmaceuticals' 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.

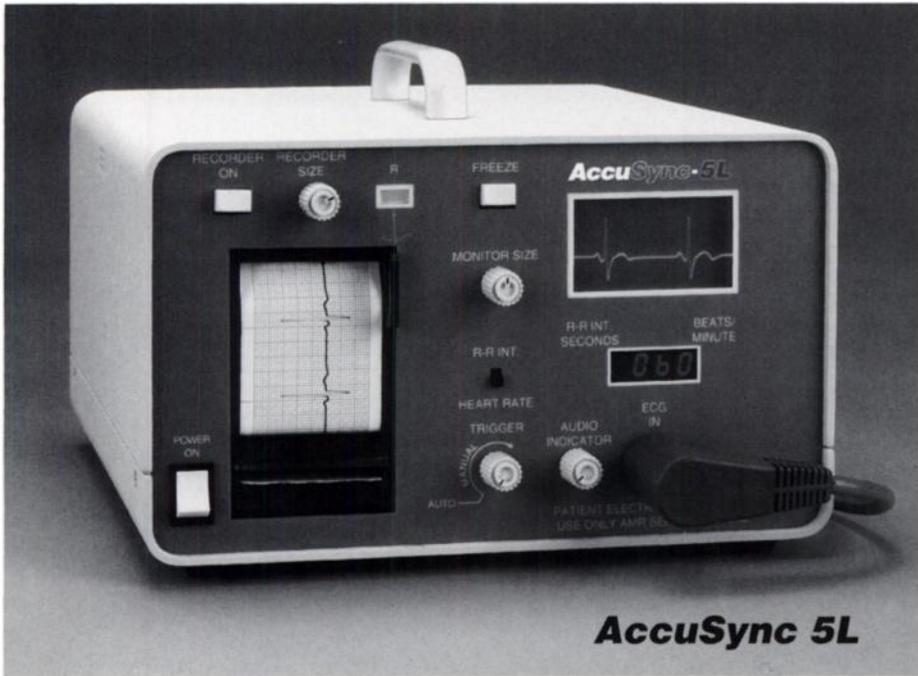
The U.S. Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material pursuant to section 35.11 and section 35.200 of Title 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States,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



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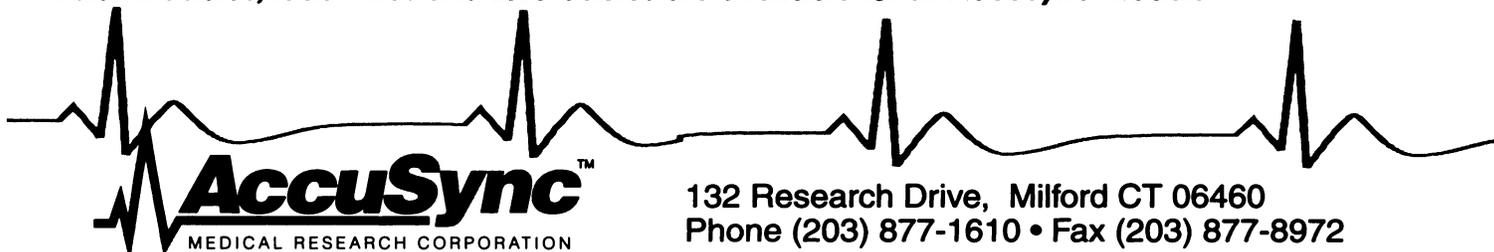
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Model	Strip Chart	CRT Monitor	HR/R-R Int	Trigger
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4M				•

Models 5L, 6L & 1L are CSA & ETL (UL544) Approved, Model 4M is CSA Approved

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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 q.s. to 1 mL
Water for Injection

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 β- 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 tissue 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 or 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)	80.6% (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 (n=42)	5 (n=38)	5 (n=33)	3 (n=27)	4 (n=22)	4 (n=22)	2 (n=11)
Placebo	3 (n=44)	3 (n=35)	2 (n=34)	0 (n=24)	1 (n=22)	1 (n=20)	0 (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.

Radioactive decay factors 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.
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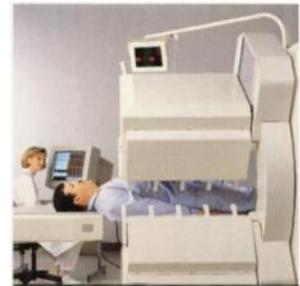
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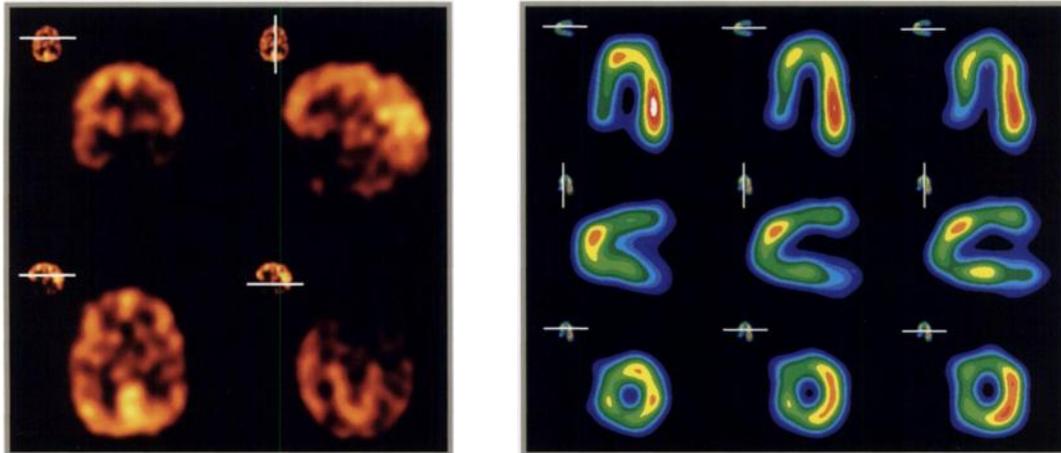
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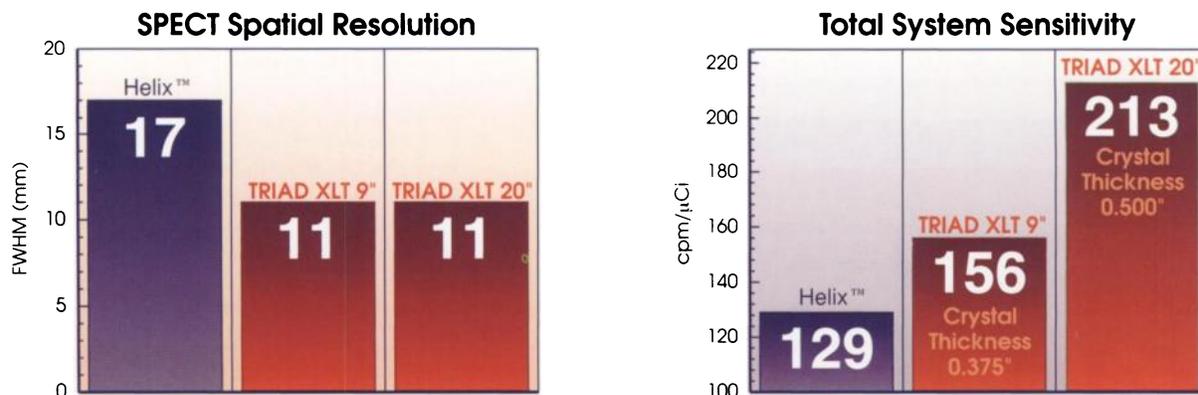
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511 keV SPECT System Performance Comparison TRIAD XLT (Triple-Head) vs. Helix™ (Dual-Head)* (Using 511 keV-optimized collimators)



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				FWHM (mm)	FWTM (mm)			
Helix™	20" x 15"	0.375	313 (142)	17	Unknown	20	64.5	129
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TRIAD XLT 20"	15" x 20"	0.500	475 (215)	11	25	15	71.0	213

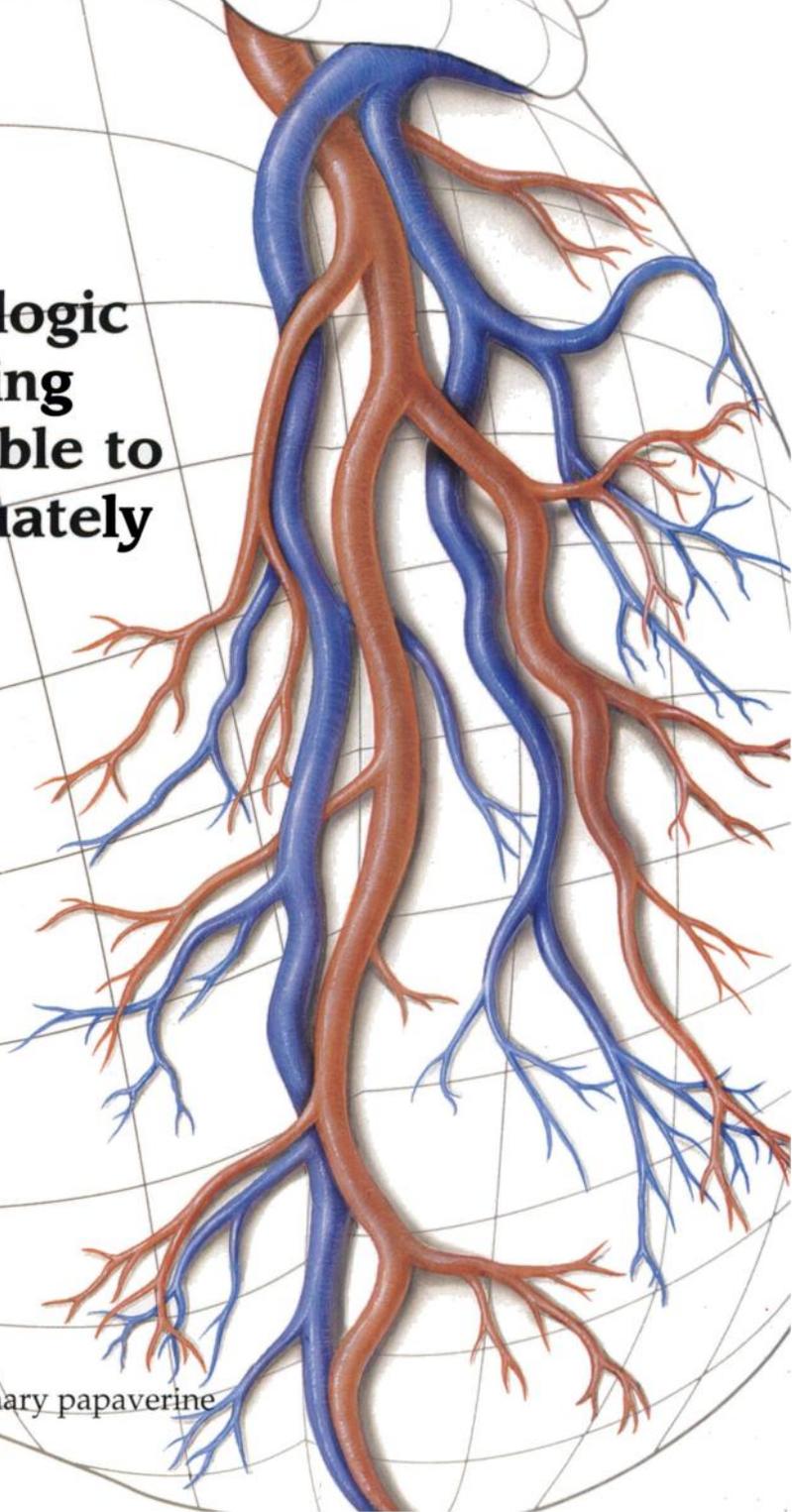
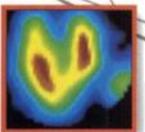
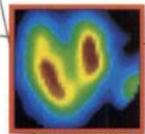
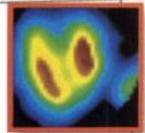
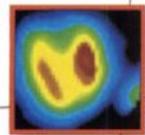
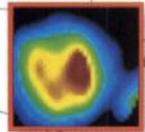
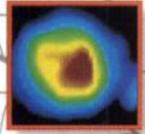
* William H. Martin, et al., "FDG-SPECT: Correlation with FDG-PET," J Nucl Med June 1995; 36: 988-995.

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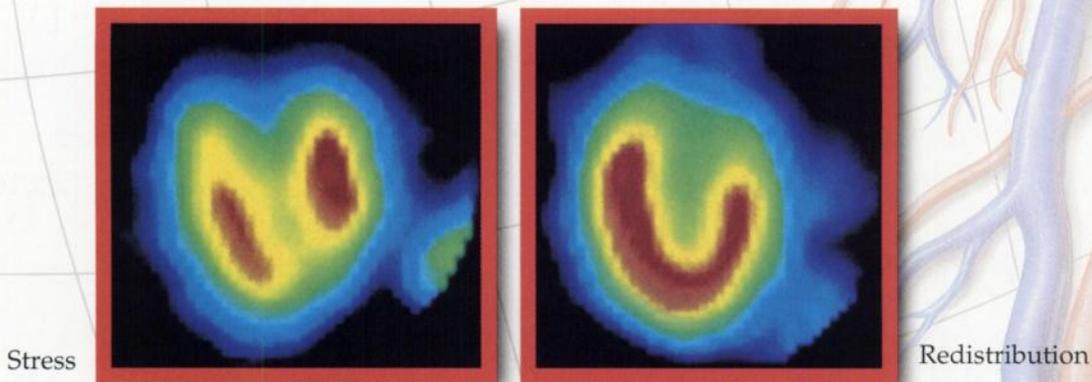
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- Most patients reach maximum coronary hyperemia*
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- Interpretable images were obtained in 98.7% of patients²

Established safety profile

- With a half-life of < 10 seconds, adverse experiences usually resolved quickly[†]
- The most common adverse experiences were flushing (44%), chest discomfort (40%) and dyspnea or the urge to breath deeply (28%)
- Contraindicated in patients with 1) 2nd- or 3rd-degree AV block, 2) sinus node disease, 3) and known or suspected bronchoconstrictive or bronchospastic lung disease (eg, asthma)
- Theophylline was used in less than 2% of patients

* Intracoronary Doppler flow catheter studies have demonstrated that a dose of intravenous Adenoscan of 140 mcg/kg/min produces maximum coronary hyperemia (relative to intracoronary papaverine) in most cases within 2-3 minutes of the onset of the infusion. Coronary blood flow velocity returns to basal levels within 1-2 minutes of discontinuing the Adenoscan infusion.

† 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.

Maximal Vasodilation* in patients unable to exercise

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- Imaging comparable to exercise
- Well established safety profile†

Recommended intravenous dose for adults is 140 mcg/kg/min infused for six minutes.

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Please see brief summary of prescribing information on adjacent page.

*Relative to intracoronary papaverine.

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

References:

1. Wilson RF, Wyche K, Christensen BV, et al. Effects of adenosine on human coronary arterial circulation. *Circulation*. 1990;82:1595-1606.
2. Cerqueira 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.

Fujisawa

Fujisawa, USA Inc.
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BRIEF SUMMARY**ADENOSCAN®**
adenosine**For Intravenous Infusion Only****DESCRIPTION**

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

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

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

INDICATIONS AND USAGE:

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

CONTRAINDICATIONS:

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

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

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

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

Sinoatrial and Atrioventricular Nodal Block

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

Hypotension

Adenoscan (adenosine) is a potent peripheral vasodilator and can cause significant hypotension. Patients with an intact baroreceptor 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_E) and reduce arterial PCO₂ causing respiratory alkalosis. Approximately 26% of patients experience breathlessness (dyspnea) or an urge to breathe deeply with Adenoscan. These respiratory complaints are transient and only rarely require intervention.

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

PRECAUTIONS:**Drug Interactions**

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Adenosine, however, like other nucleosides at millimolar concentrations present for several doubling times of cells in culture, is known to produce a variety of chromosomal alterations. In rats and mice, adenosine administered intraperitoneally once a day for five days at 50, 100, and 150 mg/kg (10-30 (rats) and 5-15 (mice) times human dosage on a mg/M² 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	26%	Upper extremity discomfort	4%	Hypotension	2%
Headache	18%	ST segment depression	3%	Nervousness	2%
Throat, neck or jaw discomfort	15%	First-degree AV block	3%	Arrhythmias	1%

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

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

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

Central Nervous System: drowsiness; emotional instability; tremors.

Genital/Urinary System: vaginal pressure; urgency.

Respiratory System: cough.

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

OVERDOSAGE:

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

DOSAGE AND ADMINISTRATION:

For intravenous infusion only.

Adenoscan should be given as a continuous peripheral intravenous infusion.

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

The required dose of thallium-201 should be injected at the midpoint of the Adenoscan infusion (i.e., after the first three minutes of Adenoscan).

Thallium-201 is physically compatible with Adenoscan and may be injected directly into the Adenoscan infusion set.

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

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

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

CAUTION: Federal law prohibits dispensing without prescription.

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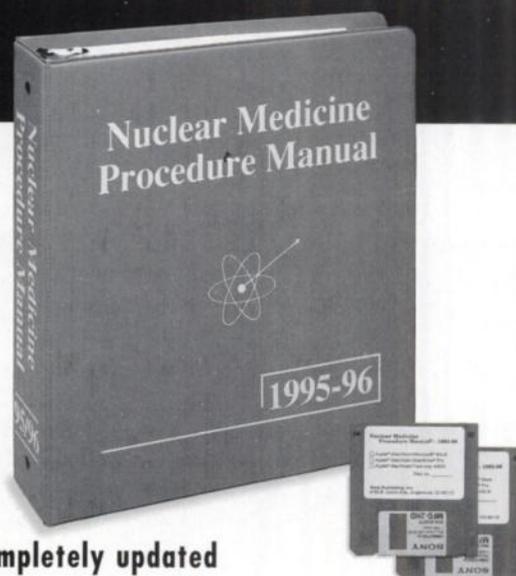
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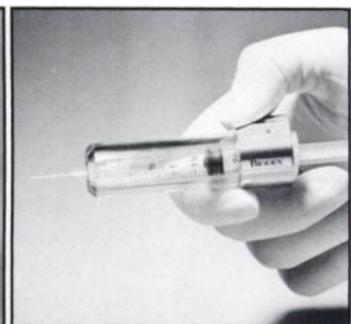
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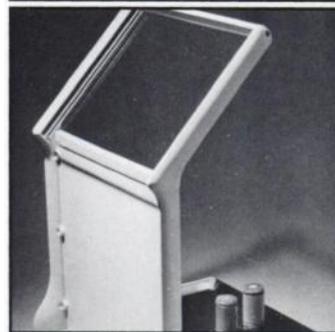
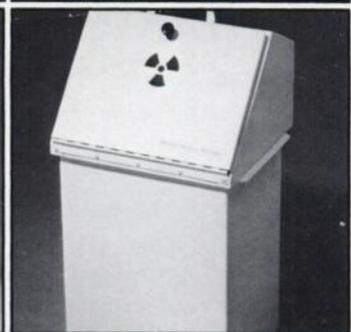


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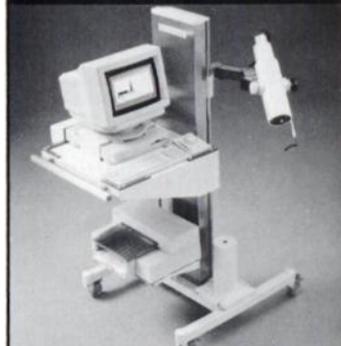
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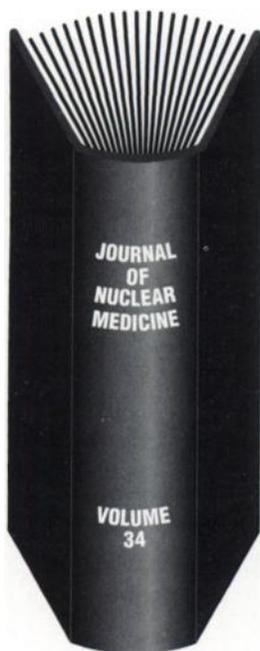
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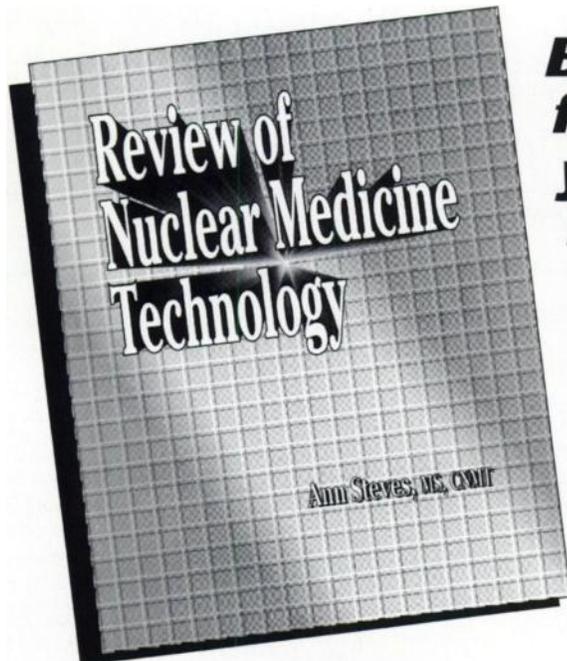
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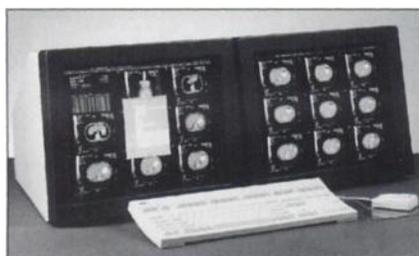
Nonuniform Attenuation Correction System



ADAC Laboratories introduces Vantage™, a nonuniform attenuation methodology correction system for use on ADAC nuclear camera systems. The Vantage correction system is a proprietary methodology that significantly improves the accuracy and quality of nuclear medicine cardiac procedures. To date, progressive health care providers are investing in techniques and equipment that offer clear

advantages in accuracy, efficiency or cost-effectiveness in the delivery of patient care. Vantage acts as an important tool in the current health care environment, providing users with strong product advantages that met the needs being voiced by health care clients. Vantage attenuation corrects for nonuniform absorption by the breast, diaphragm or other soft-tissue structures commonly presented in conventional cardiac SPECT nuclear medicine imaging procedures. The use of this new system will make it possible to correct for nonuniform attenuation, making interpretation of cardiac SPECT studies easier and more accurate. The approach is as follows: Vantage employs precise narrow-beam source geometries and patent-pending electronic scanning window techniques that eliminate scatter and minimize radiation exposure to the patient. Use of ¹⁵³Gd as the transmission source makes it possible to acquire both an emission and a transmission dataset simultaneously using efficient 180 acquisition protocols for both thallium and technetium studies. **ADAC Laboratories, R. Weatherhead, 540 Alder Drive, Milpitas, CA 95035. Phone: (408) 321-9100, ext. 2762.**

Agfa's IMPAX™ RS 3000 Network Review Stations



Agfa Technical Imaging Systems has enhanced the IMPAX RS 3000 network review station by offering several new display, image manipulation, memory and networking capabilities. The RS 3000 is a high performance station that give radiologists the ability to quickly access and review images and data acquired on the IMPAX network. A RS 3000 review station can be set up to retrieve images on request or be sent images as soon as they are available. Beyond that, an IMPAX network now supports all standard networking options, ranging from stan-

dard ethernet to ATM. For example, if a hospital has on-line Radiology Information System or Hospital Information System databases, images can automatically be accompanied by reports. Images can also be routed and prefetched on the basis of RIS activity. Both landscape (2048 X 1756) and portrait (1756 X 2048) grey scale monitors are available on the new station in either single monitor or dual-monitor configurations. Computed tomograph specialists as well as ultrasound physicians, for instance, can each view images in a way best suited to their individual needs.

The new network system also allows radiologists to perform on-screen image measurement and annotation without having to wait for a film to be printed. **Agfa Technical Imaging Systems, Thomas E. Colucci, Director, Marketing Communication, 100 Challenger Road, Ridgefield Park, NJ 07660. Phone: (201) 641-9566. Fax: (201) 440-1512.**

Easy, Fast and Affordable Teleradiology System

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PACS Test Pattern

Teleradiography, also known as Picture Archival and Communication Systems (PACS), has become a vital tool in radiology, which improves diagnostic abilities. The new PACS test pattern from Nuclear Associates provides an easy method for evaluating and solving film digitizer and laser scanning quality control problems. The test pattern detects two common problems associated with digitizing film and light leakage and film slippage. It evaluates important benchmarks of radiographic image quality including: high contrast resolution, low contrast discrimination, linearity of grey scale response, geometric distortion, reproduction of continuous fine lines and digitizer. A regular quality control procedure is mandatory to assure a diagnostic level of image quality with teleradiology and PACS. A quick, objective and reproducible quality control test is needed to ensure optimization of the film digitizer and display system. Relying on clinical images to assess digitizer performance will inevitably result in an incomplete, inaccurate and subjective evaluation. Routine use of the PACS test pattern will help eliminate any loss of resolution or dynamic range due to the display system. In addition to a quality control program for laser scanners of CCD digitizers, the PACS test pattern will detect subtle problems with image quality and provide objective evidence for documentation for easily obtainable peak performance. **Nuclear Associates, 100 Voice Road, P.O. Box 349 Carle Place, NY 11514-0349. Phone: (516) 741-6360. Fax: (516) 741-5414.**

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Clinical Director, Nuclear Medicine Service

Memorial Sloan-Kettering Cancer Center seeks an experienced Clinical Director, Nuclear Medicine Service. The individuals applying should have qualifications at the professor level, with an intended appointment as Member, Memorial Hospital and Attending Physician, Nuclear Medicine Service, American Board of Nuclear Medicine and New York State licenses mandatory. Qualifications desired include 10 or more years as leader of academic and clinical nuclear medicine programs; additional American board certification in radiology, internal medicine, radiotherapy, anatomic or clinical pathology; and an established record of scholarly publications leading to international recognition. For further information, please send C.V. and bibliography to Steven M. Larson, MD, Chief, Nuclear Medicine Service, Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, New York, NY, 10021. (212) 639-7373.

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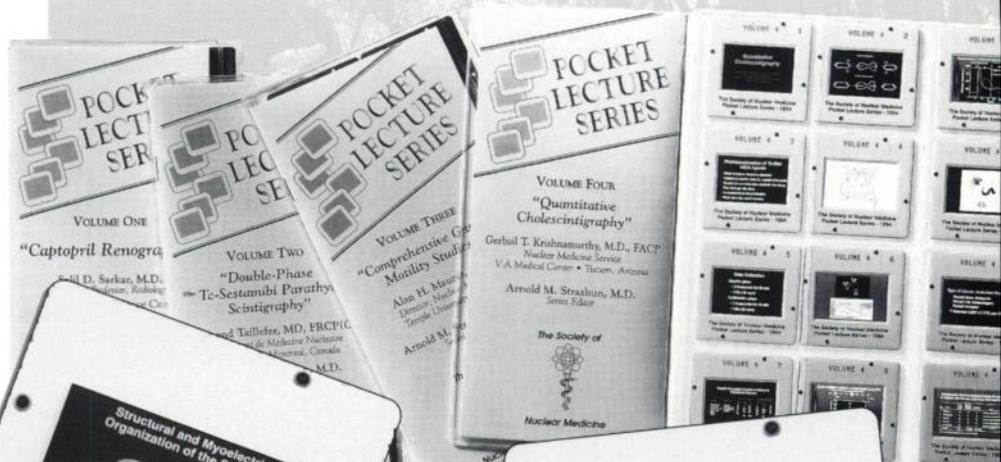
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Volume 4: "Quantitative Cholescintigraphy," Gerbail T. Krishnamurthy, MD, FACP, VA Medical Center, Tucson, AZ.

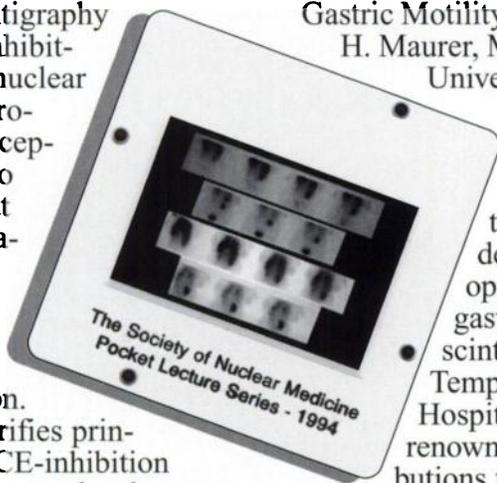
Dr. Krishnamurthy demonstrates optimal hepatobiliary scintigraphy technique by supplementing diagnostic images with accurate quantization of liver and gall bladder function. Shows how nuclear medicine physicians can now provide referring physicians a reproducible measure of gall bladder contractile function, which can uniquely answer many clinical questions.

FORTHCOMING IN 1995

Volume 5: "Combined Functional Perfusion Myocardial Perfusion Imaging," Mark D. Wittry, MD, St. Louis University Hospital, St. Louis, MO.

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PR STARS CONTEST
Syncor Pharmacy Services
20001 Prairie Street
Chatsworth, CA 91311
Fax: (818) 885-6513
Attn: Karen Pomnean, Manager
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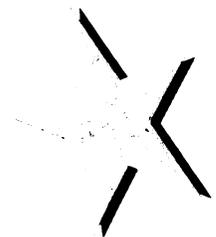
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- First Place: \$1,000 for your institution; \$350 for the entrant; up to \$1,000 for airfare to the SNM Annual Meeting to accept your award.
- Second Place: \$500 for your institution; \$250 for the entrant.
- Third Place: \$250 for your institution; \$100 for the entrant.



Please turn the page



Documentation of your activities is encouraged and may be mailed with your entry. (All original materials will be returned after the 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!*

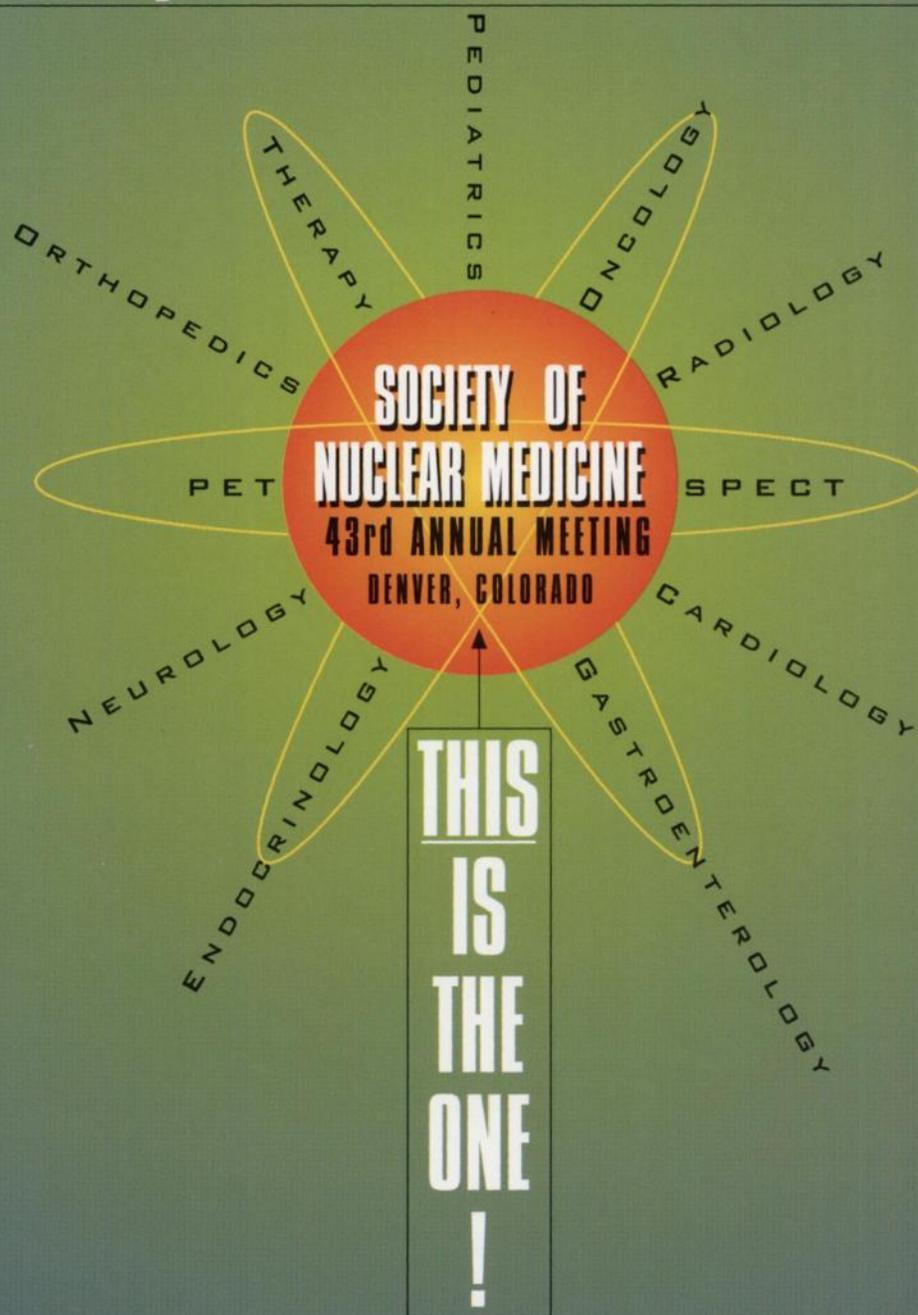
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