A versatile, disposable system

Xenon Xe 133-V.S.S. includes everything you need for a Xenon Xe 133 ventilation study. The completely disposable system includes the Xenon Xe 133 contained in a valve-shield, a CO₂ absorber and bag for rebreathing and collection of expired xenon, and a filter/mouthpiece assembly.

One system can be used for single-breath, rebreathing and wash-out studies. The valve-shield can deliver either a concentrated or a dispersed dose.

Safe, convenient assembly

Xenon Xe 133-V.S.S. can be assembled in less than a minute. Radiation exposure is minimized because there is no need to dilute the xenon gas or transfer it to a delivery system. After assembly, the ventilation study may begin immediately.

For complete information consult the package insert, a summary of which follows:

Xenon Xe 133-V.S.S. (Xenon Xe 133) Ventilation Study System

DESCRIPTION: The Xenon Xe 133-Ventilation Study System consists of a sealed frangible capsule containing 10 millicuries ±20% of Xenon Xe 133 gas at calibration time and date with less than 1% carrier xenon in air.

INDICATIONS AND USAGE: Study of pulmonary ventilation.

WARNINGS: Xenon Xe 133 should not be administered to children or to patients who are pregnant, or to nursing mothers unless the benefits to be gained outweigh the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Xenon Xe 133 should be used in pregnant women only when clearly needed.
CONSIDER MPI's
XENON Xe 133-V.S.S.
(Xenon Xe 133)
VENTILATION
STUDY SYSTEM

True, single-unit dose
The MPI Xenon Xe 133-V.S.S. contains enough Xenon Xe 133 for one ventilation study. You only use what you need and are not “locked into” an expensive delivery system that requires daily use to justify costs. Another advantage of single-unit dosage is that the risk of cross infection via reusable apparatus is significantly reduced. Further safety is afforded by the filter/mouthpiece assembly.

Reduced radiation exposure
The Xenon Xe 133 is supplied in a sealed frangible capsule. The valve-shield is designed to prevent radiation leaks during transport and use. Additionally, a shield to reduce radiation exposure to patient and attending personnel and a valve assembly to minimize the escape of exhaled xenon during washout studies are available as accessory components.

PRECAUTIONS: Xenon Xe 133 gas, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel and to patients consistent with proper patient management.

Exhaled Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of radionuclides.

Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leak-proof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers for such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic.

ADVERSE REACTIONS: Adverse reactions specifically attributable to Xenon Xe 133 have not been reported.

DOSEAGE AND ADMINISTRATION: The recommended activity range for pulmonary ventilation studies in the average patient (70 kg) is 2 to 20 millicuries (0.03 to 0.3 millicuries/kg).

HOW SUPPLIED: Each Ventilation Study System (V.S.S.) contains Xenon Xe 133 in a sealed frangible capsule containing 10 millicuries ±20% at calibration time and date stated on the label.

The sealed capsule is enclosed in a metal valve-shield which is sealed with a plastic shrink-band to prevent accidental loss of xenon during shipping. A key is provided to remove the end plugs of the valve-shield and to turn the valve fitting which breaks the sealed capsule of Xenon Xe 133. The V.S.S. also includes a disposable filter/mouthpiece assembly and a breathing-collection bag with an attached CO₂ absorber canister.

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<th>Specification Details</th>
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<tbody>
<tr>
<td>Field of View</td>
<td>16.5&quot; dia (214 sq in)</td>
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<tr>
<td>Intrinsic Resolution</td>
<td>3/32&quot; lead bars with 3/32&quot; spacing visualized using 99mTc point source over entire 16.5&quot; field</td>
</tr>
<tr>
<td>Uniformity</td>
<td>± 2% over 16.5&quot; field of view in Autocomp mode (± 10% maximum integral in uncorrected field with 20% window)</td>
</tr>
<tr>
<td>Integral Linearity Error</td>
<td>Less than ± 3%</td>
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<tr>
<td>Count Rate Capability</td>
<td>&gt;100K per sec in 20% window</td>
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<tr>
<td>Energy Resolution</td>
<td>14% F. W. H. M. with 99mTc</td>
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**Indications and Usage:** Technetium Tc 99m aggregated albumin is indicated as a lung imaging agent to be used as an adjunct in the evaluation of pulmonary perfusion.

**Contraindications:** Technetium Tc 99m aggregated albumin should not be administered to patients with severe pulmonary hypertension.

The use of Tc 99m aggregated albumin is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

**Warnings:** The possibility of allergic reactions should be considered in patients who receive multiple doses.

Theoretically, the intravenous administration of particulate material such as aggregated albumin imposes a temporary small mechanical impediment to blood flow. While this effect is probably physiologically insignificant in most patients the administration of aggregated albumin is possibly hazardous in acute cor pulmonale and other states of severely impaired pulmonary blood flow.

This radiopharmaceutical preparation should not be administered to children or to pregnant or lactating women unless the expected benefits to be gained outweigh the potential risks.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

**Precautions:** In cases of right-to-left cardiac shunt, additional risk may exist due to the rapid entry of aggregated albumin into the systemic circulation.

The contents of the kit are not radioactive. However, after the sodium pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained.

The labeling reactions involved in preparing the agent depend on maintaining the reduced state. Any oxidant present in the sodium pertechnetate Tc 99m supply may thus adversely affect the quality of the prepared agent. Hence, sodium pertechnetate Tc 99m containing oxidants, or other additives, should not be employed without first demonstrating that it is without adverse effect on the properties of the resulting agent.

The contents of the vial are sterile and non-pyrogenic. It is essential that the user follow the directions provided and adhere to strict aseptic procedures during preparation of the radiopharmaceutical.

Technetium Tc 99m aggregated albumin is physically unstable and as such the particles will settle with time. Failure to mix the vial contents adequately before use may result in non-uniform distribution of radioactivity.

It is also recommended that, because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m aggregated albumin not be used after eight hours from the time of reconstitution. Refrigerate at 2° to 8°C after reconstitution. If blood is withdrawn into the syringe, an unnecessary delay prior to injection may result in clot formation in situ.

The contents of the vial are under a nitrogen atmosphere and should be protected from air. Do not use if clumping or foaming of the contents is observed.

Accurate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m aggregated albumin should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Safety and effectiveness in children have not been established.

In as the use of any radioactive material, care should be taken to minimize radiation exposure to the patient, consistent with proper management, and to ensure minimum radiation exposure to the occupational worker.

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 governmental agency authorized to license the use of radionuclides.

**Adverse Reactions:** The literature contains reports of death occurring after the administration of aggregated albumin to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Tc 99m-labeled aggregated albumin have been reported.

Hypersensitivity reactions are possible whenever protein-containing materials such as Tc 99m-labeled aggregated albumin are used in man. Epinephrine, antihistamines and corticosteroid agents should be available for use.

**Dosage and Administration:** The recommended intravenous dose range for the average patient (70kg) is 1 to 4 millicuries. The volume of the dose may vary from 0.2 to 1.3 ml.

The recommended number of aggregated albumin particles to be administered per dose is 200,000-700,000 with the suggested number being approximately 350,000.

For ease and accuracy in dispensing the prepared agent, it is recommended that prior to reconstitution, concentrated sodium pertechnetate Tc 99m be further diluted to a volume of 8ml with fresh, preservative-free sodium chloride injection (U.S.P.).

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- Sodium chloride-10mg

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*Timpe, O. M. Precautions for Avoiding $^{133}$Xe Release From Charcoal Xenon Traps. Journal of Nuclear Medicine Technology Volume 4, Number 4, Pages 208-209.
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“In ten of the 30 scans (33%) one or more metastases not detected on the Tc-PPi [pyrophosphate] image were noted by at least two of the three readers with Tc-HEDP [Osteoscan].”

“...in three of 30 patients the Tc-PPi [pyrophosphate] scan was falsely read as normal by at least two of three readers, whereas metastatic disease was found in these patients with Tc-HEDP [Osteoscan].”

The superior lesion detection demonstrated by Osteoscan may be explained by the higher tumor to normal bone ratios obtained. In fact, it was concluded that Osteoscan “…is at present the agent of choice for routine clinical practice…”

With Osteoscan, you can also expect excellent in vitro stability (greater than 98% tag 8 hours after preparation) ...a very low tin level (.16 mg stannous chloride per vial) to minimize the potential for liver visualization or interference with subsequent brain scans ...rapid blood clearance ... plus excellent in vivo stability due to Osteoscan’s P-C-P bond.

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In Europe, contact: Philips-Duphar B.V., Cyclotron and Isotope Laboratories, Petten, Holland.

References:

Brief summary of Package Insert. Before using, please consult the full Package Insert included in each kit.

Description: Each vial of OSTEOSCAN contains 5.9 mg diphosphonate disodium, 0.16 mg stannous chloride and 0.56 mg sodium ascorbate as active ingredients. Upon addition of ADDITIVE-FREE sodium pertechnetate Tc99m the diphosphonate disodium and stannous chloride combine with Tc99m to form a stable soluble complex.

Clinical pharmacology: When injected intravenously, Tc99m-labeled OSTEOSCAN has a specific affinity for areas of altered osteogenesis. Areas of bone which are undergoing neoplastic invasion often have an unusually high turnover rate which may be imaged with Tc99m-labeled OSTEOSCAN.

Three hours after intravenous injection of Tc99m-labeled OSTEOSCAN, an estimated 40-50% of the injected dose has been taken up by the skeleton. At this time approximately 50% has been excreted in the urine and 6% remains in the blood. A small amount is retained by the soft tissue. The level of Tc99m-labeled OSTEOSCAN excreted in the feces is below the level detectable by routine laboratory techniques.

Tc99m-labeled OSTEOSCAN is also taken up in areas of necrosis and severe injury to the myocardial cells. Approximately 1.5 hours following intravenous injection 0.01-0.02 percent of the administered dose per gram of tissue is taken up by an acutely infarcted myocardium.

Indications: OSTEOSCAN is a skeletal imaging agent used to demonstrate areas of altered osteogenesis and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction. When used as an adjunct in the diagnosis of myocardial infarction the incidence of false negatives has been found to be approximately 14% and false positives approximately 16%. False negatives may result from failure to observe temporal requirements for good myocardial imaging; false positives may be related to coronary heart disease, left ventricular aneurysma, trauma, repeated cardioversion following coronary by-pass surgery or old myocardial infarcts.

Contraindications: None known.

Warnings: This radiopharmaceutical should not be administered to patients who are pregnant or lactating unless the information to be gained outweighs the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those effective in nature, of a woman of childbearing capability should be performed during the next few (approximately 10) days following the onset of menses.

The technetium used to tag the product should be routinely tested for molybdenum and aluminum; if an unacceptable level of either is found, the technetium should not be used.

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

Precautions: As in the use of any other radioactive material, care should be taken to insure minimum radiation exposure to the patient, consistent with the proper patient management, and to insure minimum radiation exposure to occupational workers.

Bone Imaging: Both prior to and following Tc99m-labeled OSTEOSCAN administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the Tc99m-labeled OSTEOSCAN injection to minimize background interference from accumulation in the bladder and unnecessary exposure to radiation.

Cardiac Imaging: Patient's cardiac condition should be stable before beginning the cardiac imaging procedure. If not contraindicated by the cardiac status, patients should be encouraged to ingest fluids and to void frequently in order to reduce unnecessary radiation exposure.

Interference from chest wall lesions such as breast tumors and healing rib fractures can be minimized by employing the three recommended projections.

Adverse reactions: None known.

Dosage and administration: The recommended adult dose of Tc99m-labeled OSTEOSCAN is 10-15 mCi. The activity of each dose should be measured by a suitable radiation calibration system just prior to administration. The dose should be given intravenously by slow injection. For optimal results bone imaging should not be done 2-4 hours post injection and cardiac imaging 6-10 hours post injection. The acute myocardial infarct can be visualized from 1-3 days following onset of symptoms with maximum uptake at 2-3 days. It is recommended that three projections of the heart be made (anterior, left anterior oblique and left lateral).
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CONTENTS (Section heads only): Quality in nuclear medicine: an introduction • The nuclear diagnostic system • Human factors • Radiopharmaceuticals • Nuclear instrumentation • In vitro assays • Conclusion • Appendixes • Procedures.

NUCLEAR MEDICINE PHYSICS, INSTRUMENTATION AND AGENTS. Edited by F. David Rollo, Ph.D., M.D.; with 12 contributors. In this exhaustive resource, physicians and nuclear medicine scientists provide a comprehensive, yet easy-to-understand look at the physical factors involved in nuclear imaging. You'll benefit from a wealth of practical information, including important discussions of physics, instrumentation and agents to help you increase your comprehension of nuclear medicine devices. 1977. 712 pp., 626 illus. Price, $54.50.

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"In ten of the 30 scans (33%) one or more metastases not detected on the Tc-PPI [pyrophosphate] image were noted by at least two of the three readers with Tc-HEDP [Osteoscan]."  

"...in three of 30 patients the Tc-PPI [pyrophosphate] scan was falsely read as normal by at least two of three readers, whereas metastatic disease was found in these patients with Tc-HEDP [Osteoscan]."  

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Description: Each vial of OSTEOSCAN contains 5.9 mg etidronate disodium, 0.16 mg stannous chloride and 0.56 mg sodium ascorbate as active ingredients. Upon addition of ADDITIVE-FREE sodium pertechnetate Tc99m the etidronate disodium and stannous chloride combine with Tc99m to form a stable soluble complex.  

Clinical pharmacology: When injected intravenously, Tc99m-labeled OSTEOSCAN has a specific affinity for areas of altered osteogenesis. Areas of bone which are undergoing neoplastic invasion often have an unacceptably high turnover rate which may be imaged with Tc99m-labeled OSTEOSCAN.  

Three hours after intravenous injection of Tc99m-labeled OSTEOSCAN, an estimated 40-50% of the injected dose has been taken up by the skeleton. At this time approximately 50% has been excreted in the urine and 6% remains in the blood. A small amount is retained by the soft issue. The level of Tc99m-labeled OSTEOSCAN excreted in the feces is below the level detectable by routine laboratory techniques.  

Tc99m-labeled OSTEOSCAN is also taken up in areas of necrosis and severely injured myocardial cells. Approximately 1.5 hours following intravenous injection 0.01-0.02 percent of the administered dose per gram of tissue is taken up by an acutely infarcted myocardium.  

Indications: OSTEOSCAN is a skeletal imaging agent used to demonstrate areas of altered osteogenesis and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction. When used as an adjunct in the diagnosis of myocardial infarction the incidence of false negatives has been found to be approximately 14% and false positives about 16%. False negatives may result from failure to observe temporal requirements for good myocardial imaging; false positives may be related to coronary heart disease, left ventricular aneurysms, trauma, repeated cardiovascular following coronary by-pass surgery or old myocardial infarcts.  

Contraindications: None known.  

Warnings: This radiopharmaceutical should not be administered to patients who are pregnant or lactating unless the information to be gained outweighs the potential hazards.  

Radioisotopes used in radiopharmaceuticals, especially those electrolyte in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menstruation.  

The technetium used to tag the product should be routinely tested for molybdenum and aluminum; at an unacceptable level of either is found, the technetium should not be used.  

Radioisotopes should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agency.  

Precautions: As in the use of any other radiopharmaceutical, care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers.  

Bone Imaging:  

Before and following Tc99m-labeled OSTEOSCAN administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the Tc99m-labeled OSTEOSCAN injection to minimize background interference from accumulation in the bladder and unnecessary exposure to radiation.  

Cardiac Imaging:  

Patient's cardiac condition should be stable before beginning the cardiac imaging procedure. If not contraindicated by the cardiac status, the patient should be encouraged to ingest fluids and to void frequently in order to reduce unnecessary radiation exposure.  

Interference from chest wall lesions such as breast tumors and healing rib fractures can be minimized by employing the three recommended projections.  

Adverse reactions: None known.  

Dosage and administration: The recommended adult dose of Tc99m-labeled OSTEOSCAN is 10-15 mCi. The activity of each dose should be measured by a suitable radiation calibration system just prior to administration. The dose should be given intravenously by slow injection. For optimal results bone imaging should be done 2-4 hours post injection and cardiac imaging 1-1½ hours post injection. The acute myocardial infarct can be visualized from 1-3 days following onset of symptoms with maximum uptake at 2-3 days. It is recommended that three projections of the heart be made (anterior, left anterior oblique and left lateral).
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CONTENTS (Section heads only): Quality in nuclear medicine: an introduction • The nuclear diagnostic system • Human factors • Radiopharmaceuticals • Nuclear instrumentation • In vitro assays • Conclusion • Appendixes • Procedures.

NUCLEAR MEDICINE PHYSICS, INSTRUMENTATION AND AGENTS. Edited by F. David Rollo, Ph.D., M.D.; with 12 contributors. In this exhaustive resource, physicians and nuclear medicine scientists provide a comprehensive, yet easy-to-understand look at the physical factors involved in nuclear imaging. You'll benefit from a wealth of practical information, including important discussions of physics, instrumentation and agents to help you increase your comprehension of nuclear medicine devices. 1977. 712 pp., 625 illus. Price, $54.50.

CONTENTS: Atomic and nuclear physics • Radioactivity and properties of nuclear radiation • Basic electronics • Applied electronics • Detection and measurement of nuclear radiation • Anger scintillation camera • Special imaging devices • Quality assurance in nuclear medicine • Operation and quality control of the rectilinear scanner • Factors affecting image formation • Evaluating imaging devices • Computers in nuclear medicine • Nuclear medicine statistics • Dose estimate techniques • Radiation safety • Principles, properties, and quality control of nuclear medicine agents • Appendixes

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THE JOURNAL OF NUCLEAR MEDICINE
If you've waited until now to get started in cardiovascular nuclear medicine...

Thallous Chloride
TI 201

New England Nuclear
To help rule out, confirm or evaluate

**Coronary artery disease**

**Positive stress ECG without angina**

*History*
A.C., 50-year-old accountant, asymptomatic, required to undergo exercise ECG as part of “executive physical.”

*ECG findings*
Normal at rest, 2.5-3 mm ST-segment depression on exercise; denied accompanying angina.

*Thallium-201 imaging*
Large apical defect on immediate post-exercise anterior view; defect filled in on delayed images.

*Working diagnosis*
Coronary artery disease, confirmed on preoperative angiography.

**Acute myocardial infarction**

**Early diagnosis**

*History*
J.B., 54-year-old construction worker, admitted to CCU following episode of severe chest pain, diaphoresis, dizziness. Patient fell to ground upon onset of symptoms, severely bruising left thigh, chest wall. No history of angina pectoris or prior MI; ECG documented left bundle branch block.

*Serum enzymes, ECG*
Elevated shortly following admission; isoenzyme analysis unavailable to differentiate elevation secondary to trauma from possible elevation secondary to acute MI; ECG nondiagnostic because of LBBB.

*Thallium-201 imaging*
Images made upon admission displayed anterior wall defect (anterior view), large septal defect (LAO view).

*Working diagnosis*
Extensive anteroseptal MI.
To start using thallium-201 in your department, you’ll need:

A recent model 37 photomultiplier tube camera with all-purpose collimator, capable of resolving 1 cm line separations on an Au 195 line phantom.

Treadmill or bicycle ergometer and ECG recorder, to perform maximal stress testing in accordance with good clinical practice.

Ability to begin imaging promptly (within 3–5 minutes) following thallous chloride Tl 201 injection and termination of stress.

To get the most out of thallium-201’s total diagnostic capability, you’ll want:

Clinical training in scan interpretation at an institution experienced in thallium-201 imaging.*

Electronic image acquisition and processing, to help resolve ambiguous studies.

Mobile imaging/acquisition instrumentation, to facilitate acute MI thallium-201 studies when patients cannot be transported to the nuclear medicine department.

Continuing medical education on thallium-201, for your staff and for your referring physicians.*

*Your NEN representative may help recommend an institution in your area. For continuing medical education programming, ask your NEN representative or write: Teaching Program Administrator, New England Nuclear, 549 Albany Street, Boston, Mass. 02118.

Thallous Chloride Tl 201

NEN New England Nuclear
Thallous Chloride
TI201
November 1977

FOR DIAGNOSTIC USE

DESCRIPTION: Thallous Chloride TI 201 is supplied in isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. The aqueous solution at calibration time contains 1mCi/ml Thallous Chloride TI 201, adjusted to pH 4.5-6.5 by the addition of hydrochloric acid and/or sodium hydroxide solution. It is made isotonic with 0.9% sodium chloride and is preserved with 0.3% benzyl alcohol. Thallium TI 201 has a half-life of 73.1 hours and is cyclotron-produced. It is essentially carrier-free, and contains less than 0.25% lead Pb 203 and less than 1.9% Thallium TI 202.

PHYSICAL CHARACTERISTICS
Thallium TI 201 decays by electron capture to Mercury Hg 201 with a physical half-life of 73.1 hours. Photons that are useful for detection and imaging are listed in Table 1. The lower energy X-rays obtained from the Mercury Hg 201 daughter of TI 201 are recommended for myocardial imaging, because the mean %/disintegration at 68-80.3 keV is much greater than the combination of gamma-4 and gamma-6 mean %/disintegration.

Table 1. Principal Radiation Emission Data

<table>
<thead>
<tr>
<th>Radiation</th>
<th>Mean %/Disintegration</th>
<th>Mean Energy (keV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-4</td>
<td>2.65</td>
<td>135.3</td>
</tr>
<tr>
<td>Gamma-6</td>
<td>10.0</td>
<td>167.4</td>
</tr>
<tr>
<td>Mercury X-rays</td>
<td>94.5</td>
<td>68-80.3</td>
</tr>
</tbody>
</table>

Martin, M.J. Nuclear Data Project, ORNL, January 1977

EXTERNAL RADIATION

The specific gamma ray constant for Thallium TI 201 is 0.47R/mCi-hr at 1 cm. The first half-value layer is 0.23mm of lead. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from the interception of various thicknesses of lead (Pb) is shown in Table 2. For example, the use of 4.4mm of lead will decrease the external radiation exposure by a factor of about 10,000.

Table 2. Radiation Attenuation By Lead Shielding

<table>
<thead>
<tr>
<th>mm of Lead (Pb)</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.23</td>
<td>10^-5</td>
</tr>
<tr>
<td>0.33</td>
<td>10^-4</td>
</tr>
<tr>
<td>1.9</td>
<td>10^-3</td>
</tr>
<tr>
<td>3.1</td>
<td>10^-2</td>
</tr>
<tr>
<td>4.4</td>
<td>10^-1</td>
</tr>
<tr>
<td>5.7</td>
<td>10^-0</td>
</tr>
</tbody>
</table>

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals before and after calibration are shown in Table 3.

Table 3. Thallium TI 201 Decay Chart: Half-Life 73.1 Hours

<table>
<thead>
<tr>
<th>Fraction Remaining</th>
<th>Fraction Remaining</th>
<th>Fraction Remaining</th>
<th>Fraction Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours Remaining</td>
<td>Hours Remaining</td>
<td>Hours Remaining</td>
<td>Hours Remaining</td>
</tr>
<tr>
<td>.72</td>
<td>1.98</td>
<td>18</td>
<td>0.84</td>
</tr>
<tr>
<td>.45</td>
<td>1.77</td>
<td>24</td>
<td>0.80</td>
</tr>
<tr>
<td>.48</td>
<td>1.58</td>
<td>30</td>
<td>0.75</td>
</tr>
<tr>
<td>.36</td>
<td>1.41</td>
<td>36</td>
<td>0.71</td>
</tr>
<tr>
<td>.36</td>
<td>1.34</td>
<td>42</td>
<td>0.67</td>
</tr>
<tr>
<td>.6</td>
<td>1.06</td>
<td>48</td>
<td>0.63</td>
</tr>
<tr>
<td>0</td>
<td>1.00</td>
<td>54</td>
<td>0.60</td>
</tr>
<tr>
<td>.12</td>
<td>1.58</td>
<td>57</td>
<td>0.54</td>
</tr>
<tr>
<td>12</td>
<td>0.90</td>
<td>66</td>
<td>0.54</td>
</tr>
</tbody>
</table>

*Calibration Time

CLINICAL PHARMACOLOGY: Carrier-free Thallous Chloride TI 201 has been found to accumulate in viable myocardium in a manner analogous to potassium. Experiments employing labeled microspheres in human volunteers have shown that the myocardial distribution of Thallous Chloride TI 201 correlates well with regional perfusion. In clinical studies, thallium images have been found to visualize areas of infarction confirmed by electrocardiographic and enzyme changes. Regions of transient myocardial ischemia corresponding to areas perfused by coronary arteries with partial stenoses have been visualized when thallium was administered in conjunction with an exercise stress test. It is usually not possible to differentiate recent from old myocardial infarction, and no exact differentiation can be made between recent myocardial infarction and ischemia. After intravenous administration, Thallous Chloride TI 201 clears rapidly from the blood with maximal concentration by normal myocardium occurring at about ten minutes.

INDICATIONS AND USAGE: Thallous Chloride TI 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction. It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

CONTRAINdications: None known.

WARNINGS: In studying patients in whom myocardial infarction or ischemia is known or suspected, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

Ideally, examinations using radiopharmaceuticals should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

The estimated absorbed radiation dose to an average adult (70kg) from an intravenous injection of a maximum dose of 1.5 millicuries of TI 201 is shown in Table 4.

Table 4. Radiation Dose Estimates of Thallous Chloride TI 201: Absorbed Dose/1mCi

<table>
<thead>
<tr>
<th>Organ</th>
<th>Rads/1mCi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
<td>0.51</td>
</tr>
<tr>
<td>Small Intestines</td>
<td>0.87</td>
</tr>
<tr>
<td>Kidneys</td>
<td>2.2</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.93</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.51</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.85</td>
</tr>
<tr>
<td>Testes</td>
<td>0.81</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.81</td>
</tr>
<tr>
<td>Total Body</td>
<td>0.36</td>
</tr>
</tbody>
</table>

Values listed include a maximum correction of 10% to the radiation doses from TI 201 due to the radiocarbons Pb 203 and TI 202.

NOW SUPPLIED: Thallous Chloride TI 201 for intravenous administration is supplied as a sterile, non-pyrogenic solution containing at calibration time, 1mCi/ml of Thallous Chloride TI 201, 9mg/ml sodium chloride, and 9mg/ml of benzyl alcohol. The pH is adjusted to between 4.5-6.5 with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radioactivity: 1.5, 3.0, 4.5, 6.0, and 9.0 millicuries of Thallous Chloride TI 201.

The contents of the vial are radioactive. Adequate shielding and handling precautions must be maintained.

Catalog Number NRP-427
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NEN Thallium 201 phantom at 2" distance from collimator.
500K

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<table>
<thead>
<tr>
<th>Picker</th>
<th>Improved Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>75%</td>
</tr>
<tr>
<td>2C</td>
<td>50%</td>
</tr>
<tr>
<td>3C, 4-12</td>
<td>40%</td>
</tr>
<tr>
<td>1/8&quot;</td>
<td>20%</td>
</tr>
</tbody>
</table>

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As nuclear medicine has matured and progressed so has the development of the Ultra-Technetium* FM Tc 99m Generator. In keeping pace with the changing needs of the nuclear medicine community, we have redesigned the Ultra-Technetium system and further refined those features that have, through the years, made the Ultra-Technetium Generators among the safest, easiest-to-operate, and most reliable performing technetium delivery systems in the world.

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- New valve system:
  Provides positive protection against accidental elution or leakage.

- Better shielding:
  To reduce radiation levels during elution, an additional lead plate has been inserted inside between the tubing and the canister.

  A redesigned auxiliary shield is available that provides added reduction in surface radiation levels on all sides and the top.

- Reduced weight (smaller units):
  A change in the configuration of the internal column shield allows weight reduction of our smaller generators.

See following page for brief summary.
INTRODUCING...
Our latest Evolutionary Technetium delivery system.

Ultra-TechneKow® FM
(Technetium Tc-99m Generator)
For the Production of Sodium Pertechnetate Tc 99m

DESCRIPTION
The Ultra-TechneKow FM Generator is prepared with fission-produced molybdenum-99. This generator provides a closed system for the production of sterile metastable technetium-99m, which is produced by the decay of molybdenum-99. Sterile, pyrogen-free isotonic solutions of Sodium Pertechnetate Tc 99m can be obtained conveniently by periodic aseptic elution of the generators. These solutions should be crystal clear.

The generator consists of a sealed glass chamber containing specially processed alumina. This treated alumina has a high absorption capacity for molybdenum-99 and a low affinity for technetium-99m. As a result, elution of the generator yields a solution of technetium-99m containing negligible amounts of molybdenum-99.

ACTIONS
The pertechnetate ion distributes in the body similarly to the iodide ion but is not organified when trapped in the thyroid gland. Pertechnetate tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. It also concentrates in thyroid gland, salivary glands, stomach and choroid plexus. After intravascular administration it remains in the circulatory system for sufficient time to permit blood pool, organ perfusions, and major vessel studies. It gradually equilibrates with the extracellular space. A fraction is promptly excreted via the kidneys.

INDICATIONS
Sodium pertechnetate Tc-99m is used for brain imaging, thyroid imaging, salivary gland imaging, placenta localization and blood pool imaging.

CONTRAINDICATIONS
None.

WARNINGS
This radiopharmaceutical should not be administered to patients who are pregnant or during lactation unless the information to be gained outweighs the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

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

PRECAUTIONS
As in the use of any other radioactive material, care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers.

At the time of administration the solution should be crystal clear.

ADVERSE REACTIONS
None.

DOSED AND ADMINISTRATION
Sodium pertechnetate Tc-99m is usually administered by intravascular injection but can be given orally. The dosage employed varies with each diagnostic procedure.

The suggested dose range employed for various diagnostic indications in the average patient (70 kg) is:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain imaging</td>
<td>10 to 20 mCi</td>
</tr>
<tr>
<td>Thyroid gland imaging</td>
<td>1 to 10 mCi</td>
</tr>
<tr>
<td>Salivary gland imaging</td>
<td>1 to 5 mCi</td>
</tr>
<tr>
<td>Placenta localization</td>
<td>1 to 3 mCi</td>
</tr>
<tr>
<td>Blood pool imaging</td>
<td>10 to 20 mCi</td>
</tr>
</tbody>
</table>

NOTE: Up to 1 gram of reagent grade potassium perchlorate in a suitable base or capsule may be given orally prior to administration of sodium pertechnetate Tc-99m injection for brain imaging, placenta localization and blood pool imaging.

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

HOW SUPPLIED
The Ultra-TechneKow FM (Technetium Tc 99m) Generators contain the following amount of molybdenum-99 at the time of calibration stated on the label.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>0.25 curies</td>
</tr>
<tr>
<td>101</td>
<td>0.50 curies</td>
</tr>
<tr>
<td>106</td>
<td>0.75 curies</td>
</tr>
<tr>
<td>102</td>
<td>1.0 curies</td>
</tr>
<tr>
<td>103</td>
<td>1.5 curies</td>
</tr>
<tr>
<td>104</td>
<td>2.0 curies</td>
</tr>
<tr>
<td>105</td>
<td>2.5 curies</td>
</tr>
<tr>
<td>107</td>
<td>3.0 curies</td>
</tr>
</tbody>
</table>

Each generator is supplied with the following components for the elution of the generator:

6—Sterile, graduated, evacuated collecting vials
6—Sterile Luer-Lock needles with plastic covers
6—Pressure-sensitive “Caution—Radioactive Material” collecting vial labels
6—Pressure-sensitive radioassay data labels for lead dispensing shield

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Results obtained using the Dymax-MB Mobile Camera with its powerful minicomputer data processor, clearly demonstrate the advantages of radiocardiology as a diagnostic technique. Dymax-MB is compact, fully mobile and simple to operate. The camera produces studies with excellent resolution and uniformity at both low and high countrates, while the self-contained processor provides instant clinical analysis of the data. Among the heart functions which can be studied "live" are wall motion, ejection fraction, cardiac output, interventricular shunts and other parameters of major importance.

Analytical procedures are speeded by automatic repeat of previously established protocols. On-the-spot analysis enables the attending physician to immediately evaluate results, eliminating the delays of batch processing at a central installation, thus maximising the efficacy of the Dymax-MB.

Check for yourself the significant advantages of this highly efficient clinical tool.

You can:
- Spare your patient the trauma of catheterization.
- Complete the diagnosis at the patient's bed-side, sparing him exhausting movement to overburdened laboratories.
- Receive pre-processed data for more rapid and detailed interpretation than was possible with earlier techniques.

Until you examine the performance of this outstanding unit, you haven't heard the last word. Call us or write for more information or demonstration.

The Elscint commitment to excellence
“Perhaps the greatest contribution of bone imaging is its superiority over conventional radiography in the detection of metastatic bone tumors.”

In oncology...
for reliable early detection of bone metastases:

Most rapid blood clearance²
- At 90 minutes postinjection, blood clearance of MDP pharmacologically identical to OSTEOLITE was approximately equal to that of tested pyrophosphate agents at 6 hours postinjection.
- At 3 hours, MDP blood levels were considerably less than those of tested EHDP and pyrophosphate.
Result: low-background studies, whether you must scan early to meet patient-flow demands, or at 3 hours for more optimal image detail.

Lowest soft tissue activity²,³
The “difference in soft tissue activity (highest with polyphosphate and lowest with MDP) is discernible in clinical images.”²
A University of Minnesota study found that only 4% of 175 MDP images showed moderate to marked soft tissue activity, compared to 17% of EHDP images.³
Result: highest assurance of visualizing all skeletal structures.

Highest target-to-background differential⁴
OSTEOLITE’s rapid blood clearance and lower soft tissue uptake usually enable current gamma cameras to resolve peripheral skeletal structures and phalanges.
Result: confidence of detecting resolution-challenging alterations in osteogenesis...even roentgenographically “invisible” fractures and small metastases.

Convenient storage and preparation
Available in 5-vial or 30-vial “Convenience Packs,” OSTEOLITE can be stored and used at room temperature (15–30°C).

REFERENCES:
3. Forstrom L et al: Data on file at New England Nuclear, Medical Diagnostics Division, North Billerica, MA
A 19-year-old male with known eosinophilic granuloma involving the mandible bilaterally was referred for a bone scan to rule out occult sites of involvement. Bone imaging with OSTEOLITE showed increased uptake in the rami of the mandible on both sides. The medial portion of the mandible anteriorly and the remainder of the skull, the spine, ribs, pelvis and long bones show no abnormalities suggestive of multiple foci of disease. The increased area of uptake around the left ankle was attributed to soft tissue swelling due to a recent ankle sprain.

Images produced with 20.5 mCi technetium-99m labeled OSTEOLITE; spot images recorded at 500 K counts. Searle LFOV™ camera with Micro Dot™ Imager.
OSTEOLlTE
Technetium Tc 99m Medronate Sodium Kit (Formerly Known as MDP)

DESCRIPTION: New England Nuclear’s OSTEOLITE™ Technetium Tc 99m Medronate Sodium Kit (formerly known as MDP), is supplied sterile and non-pyrogenic in lyophilized kit form suitable for reconstitution with sodium pertechnetate Tc 99m to form a diagnostic skeletal imaging agent for intravenous administration. Each vial contains 10ng medronate disodium, and 0.55mg stannous chloride dihydrate; pH is adjusted between 7.0–7.5 with hydrochloric acid and/or sodium hydrosulfite solution. The contents of the vial are lyophilized and stored under nitrogen.

PHYSICAL CHARACTERISTICS: Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours. (SOURCE: Martin, M. J. Nuclear Data Project, Oak Ridge National Laboratory, March, 1976) Photons that are useful for imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data — Technetium Tc 99m

| Mean %| Mean Energy (ev) | Gamma-2 | 88.96 | 140.5 |

To facilitate correction for physical decay of Technetium Tc 99m, the fractions of initial activity that remain at selected intervals after the time of calibration are shown in Table 2.

Table 2. Physical Decay Chart — Technetium Tc 99m Half-Life 6.02 Hours

<table>
<thead>
<tr>
<th>Fraction Remaining</th>
<th>Hours</th>
<th>Hours Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00</td>
<td>1000</td>
<td>8</td>
</tr>
<tr>
<td>1.98</td>
<td>891</td>
<td>9</td>
</tr>
<tr>
<td>2.91</td>
<td>794</td>
<td>10</td>
</tr>
<tr>
<td>3.61</td>
<td>708</td>
<td>11</td>
</tr>
<tr>
<td>4.27</td>
<td>631</td>
<td>12</td>
</tr>
<tr>
<td>4.81</td>
<td>562</td>
<td>13</td>
</tr>
<tr>
<td>5.34</td>
<td>501</td>
<td>14</td>
</tr>
<tr>
<td>5.84</td>
<td>477</td>
<td>15</td>
</tr>
</tbody>
</table>

*Calibration Time

EXTERNAL RADIATION: The specific gamma ray constant for Technetium Tc 99m is 0.8/450 mCi/hr at 1cm. The half value layer is 0.22cm of Pb. To facilitate control of radiation exposure from milliureas of Technetium Tc 99m, the use of a 6.35mm thick standard radiation filtration lead shield will attenuate the radiation emitted by a factor greater than 10³.

Table 3. Radiation Attenuation by Lead Shielding

<table>
<thead>
<tr>
<th>Shield Thickness (Pb)</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>0.95</td>
<td>10^-1</td>
</tr>
<tr>
<td>1.8</td>
<td>10^-2</td>
</tr>
<tr>
<td>2.7</td>
<td>10^-3</td>
</tr>
<tr>
<td>3.6</td>
<td>10^-4</td>
</tr>
<tr>
<td>4.5</td>
<td>10^-5</td>
</tr>
<tr>
<td>5.4</td>
<td>10^-6</td>
</tr>
<tr>
<td>6.3</td>
<td>10^-7</td>
</tr>
</tbody>
</table>

CLINICAL PHARMACOLOGY: Upon intravenous injection, Technetium Tc 99m OSTEOLITE exhibits a specific affinity for areas of altered osteogenesis. In humans, blood levels fall to 4-10% of the injected dose by two hours post-injection and to 3-5% by three hours. During the first 24 hours following its administration in patients with normal renal function, 50-75% of the radioactivity is excreted into the urine and less than 2% of the injected dose remains in the vascular system.

Uptake of the Technetium Tc 99m in bone appears to be related to osteogenic activity and to skeletal blood perfusion. The deposition in the skeleton is bilaterally symmetrical, with increased accumulation in the axial structure as compared to the appendicular skeleton. There is increased activity in the distal aspect of long bones as compared to the diaphyses. In pediatric patients, in whom the epiphysial centers are still open, there is more marked accumulation of the radiopharmaceutical in the distal aspects of long bones than is seen in adults in whom the epiphyssal centers are closed. Localized areas of abnormal accumulation of the radiopharmaceutical may be seen in primary skeletal malignancies, metastatic malignancies to bone, acute or chronic osteomyelitis, arthritides, recent fractures, areas of ectopic calcification, Paget’s disease, regional migratory osteopetrosis, areas of acute, necrosis and, in general, any pathological situation involving bone in which there is increased osteogenic activity or localized increased osseous blood perfusion. Since increased osteogenic activity and localized increased osseous blood perfusion are not usually present in chronic bone diseases, bone imaging agents, in general, are not effective in detecting such diseases. Localized areas of decreased accumulation of the radiopharmaceutical may be noted in areas of bone which have received localized fields of external radiation or to which blood flow has been interrupted. OSTEOLITE has also been noted to accumulate in areas of acute myocardial infarction from one to fourteen days after the pathologic event.

INDICATIONS AND USAGE: Technetium Tc 99m OSTEOLITE may be used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINDICATIONS: None known.

WARNING: The contents of the OSTEOLITE vial are intended only for use in the preparation of Technetium Tc 99m medronate sodium and are NOT to be directly administered to the patient.

Ideally, examinations using radiopharmaceuticals—especially those elective in nature—of women of childbearing capability should be performed during the first ten days following the onset of menses.

PRECAUTIONS: A thorough knowledge of the normal distribution of intravenously administered Technetium Tc 99m medronate sodium is essential in order to accurately interpret pathologic studies. Technetium Tc 99m medronate sodium, as well as any radioactive agent, must be handled with care. Once sodium pertechnetate Tc 99m is added to the kit, appropriate safety measures should be used to minimize external radiation exposure to hospital personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

The Technetium Tc 99m labeling reaction involved in preparing Technetium Tc 99m medronate sodium depends on the maintenance of the ion in the divalent state. Any oxidant present in the sodium pertechnetate Tc 99m employed may adversely affect the quality of the prepared agent. Thus, sodium pertechnetate Tc 99m containing oxidants should not be used without first demonstrating that it is without adverse effect on the properties of the resulting agent.

The use of bacteriostatic sodium chloride as a diluent for sodium pertechnetate Tc 99m may adversely affect the biologic distribution of the prepared agent, and its use is not recommended.

Adequate reproduction studies have not been performed in animals to osteogenesis. Whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m medronate should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule nursing should not be undertaken when a patient is administered radioactive material.

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: None reported.

Dosage and Administration: The recommended dose for the average 70kg adult patient is 15mCi with a range of 10–20mCi. The patient dose should be measured by a suitable radioactive calibration system immediately prior to administration. Optimal imaging results are obtained within one to four hours after administration.

OSTEOLITE should be used within six hours after aspecific reconstitution with sodium pertechnetate Tc 99m. For optimum results this time should be minimized. The vial contains no bacteriostat.

Radiopharmaceuticals should be used by persons who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate governmental agencies authorized to license the use of radionuclides.

RADIATION DOSIMETRY: The estimated absorbed radiation dose to an average patient (70kg) from an intravenous injection of a maximum dose of 20 millicuries of Technetium Tc 99m OSTEOLITE is shown in Table 4.

Table 4. Absorbed Radiation Dose — Technetium Tc 99m Medronate Sodium (rads/20mCi)

<table>
<thead>
<tr>
<th>Organ</th>
<th>Total Body</th>
<th>Bone Total</th>
<th>Red Marrow</th>
<th>Kidneys</th>
<th>Liver</th>
<th>Bladder Wall</th>
<th>Ovaries</th>
<th>Testes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.13</td>
<td>0.70</td>
<td>0.56</td>
<td>0.62</td>
<td>0.16</td>
<td>2.60</td>
<td>6.20</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>4.8 hr</td>
<td>4.8 hr</td>
<td>4.8 hr</td>
<td>4.8 hr</td>
<td>4.8 hr</td>
<td>4.8 hr</td>
<td>4.8 hr</td>
<td>4.8 hr</td>
</tr>
<tr>
<td></td>
<td>2 hr vial</td>
<td>2 hr vial</td>
<td>2 hr vial</td>
<td>2 hr vial</td>
<td>2 hr vial</td>
<td>2 hr vial</td>
<td>2 hr vial</td>
<td>2 hr vial</td>
</tr>
</tbody>
</table>


HOW SUPPLIED: NEN’s OSTEOLITE™ Technetium Tc 99m Medronate Sodium Kit is supplied as a set of four or thirty vials, sterile and non-pyrogenic. Each nitrogen-flushed vial contains in lyophilized form:

Medronate Disodium — 10mg
Stannous Chloride Dihydrate — 0.85mg

The pH is adjusted to between 7.0–7.5 with hydrochloric acid and/or sodium hydrosulfite solution. The contents of the vial were lyophilized under nitrogen. Store at room temperature (15–30°C). Included in each five (5) vial kit is one (1) package insert and six (6) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels.

INSTRUCTIONS FOR PREPARATION OF TECHNETIUM Tc 99m OSTEOLITE: Asceptically inject 2 to 8m of sodium pertechnetate Tc 99m (pertechnetate in isotonic saline without a bacteriostat) into the supplied OSTEOLITE enclosed by a radiation shield. Swirl for at least ten seconds to dissolve completely. Label appropriately. Suitable labels have been supplied with each OSTEOLITE Kit. Use within six hours after reconstitution. For optimum results, this time should be minimized.

Using proper shielding, the vial containing the reconstituted solution should be visually inspected to insure that it is clear and free of particulate matter.

The contents of the kit vials are not radioactive; however, after reconstitution with sodium pertechnetate Tc 99m the contents are radioactive and adequate shielding and handling precautions used be maintained.

Do not use if there is a vacuum in the immediate drug container or if air is injected into the container when the dose is withdrawn.

Catalog Number NRP-420 (5 vial kit)
Catalog Number NRP-426C (30 vial kit)
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In North America: Amersham Corporation, Illinois 60005. Telephone: 312-593-6300
In W.Germany: Amersham Buchler GmbH & Co KG, Braunschweig. Telephone: 05307-4691
Gallium Citrate Ga 67

DESCRIPTION

Gallium Citrate Ga 67 is supplied in isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. Each milliliter contains 3 millicuries Gallium Ga 67 on the calibration date complexed with 0.67 mg sodium citrate in sodium chloride injection, U.S.P., with 0.5% benzyl alcohol v/v as a preservative. The pH is adjusted to between 5.0-8.0 with hydrochloric acid and/or sodium hydroxide solution. Gallium Ga 67, with a half-life of 78.1 hours, is cyclotron produced by the proton irradiation of Zinc Zn 66 of enriched zinc oxide and is essentially carrier-free. Gallium Ga 67 has a minimum purity of 95% with no more than 1% Gallium Ga 66 and no more than 0.05% of Zinc Zn 65.

CLINICAL PHARMACOLOGY

Carrier-free Gallium Citrate Ga 67 has been found to concentrate in certain viable primary and metastatic tumors. The mechanism of concentration is unknown, but investigational studies have shown that Gallium Ga 67 accumulates in lymphomeses and is bound to a soluble intracellular protein. It has been reported in the scientific literature that following intravenous injection, the highest tissue concentration of Gallium Ga 67—other than tumors—is in the renal cortex. After the first day, the maximum concentration shifts to bone and lymph nodes and after the first week, to liver and spleen. Gallium is excreted relatively slowly from the body. The average whole body retention is 65% after 7 days, with 20% having been excreted in the urine and 5% in the stools.

INDICATIONS AND USAGE

Gallium Citrate Ga 67 may be useful to demonstrate the presence and extent of Hodgkin's disease or lymphoma. Positive Gallium Ga 67 uptake in the absence of prior symptoms warrants follow-up as an indication of a potential disease state.

CONTRAINDICATIONS

None known.

WARNINGS

Gallium Citrate Ga 67 should not be administered to children or to patients who are pregnant or to nursing mothers unless the information to be gained outweighs the potential hazards. Ideally, examinations using radiopharmaceutical drug products, especially those elective in nature of a woman's childbearing capability should be performed during the first two (approximately ten) days following the onset of menstrual cycles.

PRECAUTIONS

A thorough knowledge of the normal distribution of intravenously administered Gallium Citrate Ga 67 is essential in order to interpret pathologic studies accurately. The finding of an abnormal gallium concentration usually implies the existence of underlying pathology, but further diagnostic studies should be done to distinguish benign from malignant lesions. Gallium Citrate Ga 67 is intended for use as an adjunct in the diagnosis of certain neoplasms. Certain pathologic conditions may yield up to 40% false negative gallium studies. Therefore, a negative study cannot be definitely interpreted as ruling out the presence of disease.

Lymphocytic lymphoma frequently does not accumulate Gallium Ga 67 sufficiently for unequivocal imaging, and the use of gallium with this histologic type of lymphoma is not recommended at this time.

Gallium Citrate Ga 67, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize external radioactivity exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients consistent with proper patient management.

No long term animal studies have been performed to evaluate carcinogenic potential. Adequate reproduction studies have not been performed in animals to determine whether this drug, affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Gallium Citrate Ga 67 should be used in pregnant women only when clearly needed.

Gallium Citrate Ga 67 has been found to accumulate in breast milk and should not be used in nursing mothers. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

No adverse reactions have been observed with Diagnostic Isotopes' Gallium Citrate Ga 67 at this time.

DOSEAGE AND ADMINISTRATION

The recommended adult (70 kg) dose of Gallium Citrate Ga 67 is 2-5 millicuries. Gallium Citrate Ga 67 is intended for intravenous administration only. Approximately 10% of the administered dose is excreted in the feces during the first week after injection. Daily locations and/or enemas are recommended from the day of injection until the final images are obtained in order to cleanse the bowel of radioactive material and minimize the possibility of false positive studies.

Studies indicate the optimal tumor to background concentration ratios are often obtained about 48 hours post-injection. However, considerable biological variability may occur in individuals, and acceptable images may be obtained as early as 6 hours and as late as 110 hours after injection. The patient dose should be measured by a suitable radioactive calibration system immediately prior to administration.

Radioisotopes should be used by persons who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agencies authorized to license the use of radionuclides.

HOW SUPPLIED

Gallium Citrate Ga 67 is supplied at a concentration of 3 millicuries/ml at the time of calibration. The contents of the vial are radioactive and adequate shielding and handling precautions must be maintained.
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Dr. Willard Smullen, right, and John LaFond, RT(R), FASRT, with the KODAK X-OMAT Processor, Model M3, which served St. Mary's Hospital in Decatur, Illinois, for 14 years with a total of 2 days out for service. It processed 1.3 million sheets of film and 61 miles of 70-mm and 16-mm film.

When you buy a processor, it may be years before you know the true cost. It all depends on how many hours of trouble-free service the processor gives you. That may be one reason KODAK RP X-OMAT Processors are virtually unmatched in performance. When you're considering processors, you'll discover there's a dependable KODAK Up-time Processor to fit your needs.

90-second processing: You're familiar with the Model M6A-N, which provides consistent high-quality, 90-second processing. Now you can get the same dependability in a new 90-second processor that uses an ambient water wash (40-90°F). Called the Model M6AW, it occupies only 5 square feet of floor space and can save you money on initial plumbing and subsequent water-heating costs.

150-second processing: The Model M7A also provides for an ambient water wash (40 to 87°F). In addition, it features an automatic standby control to decrease wear and power consumption when the processor must be left on but no films are being processed. For an even greater saving, you can order the KODAK RP X-OMAT Water Saving Kit, Model M7. This accessory turns off the water flow completely when the processor is not in use.

For special procedure radiography: The Model SP Processor is specifically designed to meet the high-volume needs of the angiographer and neuroradiologist. You have a choice of 200-second or 150-second processing. The shorter cycle can be used with all KODAK X-OMAT Films. The longer cycle extends automatic processing to include such films as KODAK BLUE BRAND Film. Film throughput speed is comparable to that of any KODAK RP X-OMAT Processor.

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- POLYPHOSPHATE
- MDP
- PHYTATE
- DTPA
- MICROSPHERES
- HUMAN SERUM ALBUMIN
- GLUCOHEPTONATE
- SULFUR COLLOID
- MACROAGGREGATED ALBUMIN

For more detailed information, contact:

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Non-preservative normal saline USP

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  Use for eluting Technetium-99m generators.

- **DILUTION:**
  Use for diluting high specific concentrations of Technetium-99m.

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SODIUM CHLORIDE INJECTION U.S.P. with LOW DISSOLVED OXYGEN
pH 4.5 to 7.0

**INDICATIONS:**
SODIUM CHLORIDE INJECTION U.S.P. with LOW DISSOLVED OXYGEN is indicated for eluting, preparing and/or diluting pharmaceuticals that specify oxidants may cause adverse effects on the final product. SODIUM CHLORIDE INJECTION U.S.P. with LOW DISSOLVED OXYGEN is also used as a fluid and electrolyte replenisher or as an irrigating solution.

**WARNING:**
Excessive amounts of sodium chloride by any route may cause hypopotassemia and acidosis. Excessive amounts by the parenteral route may precipitate congestive heart failure and acute pulmonary edema, especially in patients with cardiovascular disease, and in patients receiving corticosteroids or corticotropin drugs that may give rise to sodium retention. No antimicrobial agent has been added.

**PRECAUTIONS:**
Unused amounts should be discarded immediately following withdrawal of any portion of the contents.

**HOW SUPPLIED:**
Catalog No. 25
Product S-25
Packaging 10 ml single-dose vial contains approximately 6 ml. Each ml contains 9 mg sodium chloride providing 0.154 mEq each of sodium and chloride ions. Total osmolarity 300 mOsM/1, pH between 4.5 and 7.0. Dissolved oxygen content less than 5 ppm. Contains no preservatives.

ACKERMAN NUCLEAR, INC.
445 W. Garfield Avenue
Glendale, Calif. 91204

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**Decrease the amount of oxygen you add daily and reduce the effect of one more variable from your radiopharmacy. Use Low Dissolved Oxygen saline when preparing kits containing any stannous tin products.**

*less than 5 ppm

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And with results like the picture shown here, our story couldn’t be clearer.

Computer enhanced scintigram of left adrenal adenoma in Cushings Syndrome. Nuclear Enterprises Mk-3 gamma-camera 2.6 day post injection of Scintadren (kidneys localized with SmCit 99m-Te DTPA) R. Marz, Department of Nuclear Medicine, University Hospital, Hamburg, F.D.R.

Full information is available on request.
The Radiochemical Centre Limited, Amersham, England.
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<thead>
<tr>
<th>1979 GE MEDICAL EDUCATION PROGRAMS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RADIOLOGY PROGRAMS</strong></td>
</tr>
<tr>
<td>Understanding X-ray Generation I</td>
</tr>
<tr>
<td>Standardization of Radiologic Techniques II</td>
</tr>
<tr>
<td>Quality Assurance in Radiology III</td>
</tr>
<tr>
<td>Introduction to Radiologic Techniques</td>
</tr>
<tr>
<td>Radiology Registration &amp; Certification</td>
</tr>
<tr>
<td>Advanced Concepts in Diagnostic Imaging*</td>
</tr>
<tr>
<td><strong>COMPUTED TOMOGRAPHY PROGRAMS</strong></td>
</tr>
<tr>
<td>Principles of Computerized Tomography I</td>
</tr>
<tr>
<td>Quality Control in Computerized Tomography II</td>
</tr>
<tr>
<td>Quality Assurance in Computerized Tomography III</td>
</tr>
<tr>
<td>Advanced Concepts in Diagnostic Imaging*</td>
</tr>
<tr>
<td><strong>NUCLEAR MEDICINE PROGRAMS</strong></td>
</tr>
<tr>
<td>Basics of Nuclear Medicine</td>
</tr>
<tr>
<td>Quality Control &amp; Compliance in Nuclear Medicine</td>
</tr>
<tr>
<td>Advanced Concepts of Nuclear Medicine</td>
</tr>
<tr>
<td>Dynamics in Nuclear Medicine</td>
</tr>
<tr>
<td>Nuclear Cardiology</td>
</tr>
<tr>
<td>Comprehensive Nuclear Medicine</td>
</tr>
<tr>
<td>Radiopharmaceutical Techniques</td>
</tr>
<tr>
<td>Advanced Concepts in Diagnostic Imaging*</td>
</tr>
<tr>
<td>Radioisotope Handlers</td>
</tr>
<tr>
<td><strong>MONITORING PROGRAM</strong></td>
</tr>
<tr>
<td>Principles of Cardiovascular Monitoring</td>
</tr>
<tr>
<td><strong>ULTRASOUND PROGRAMS</strong></td>
</tr>
<tr>
<td>Basics of Ultrasound I</td>
</tr>
<tr>
<td>Quality Control &amp; Compliance in Ultrasound II</td>
</tr>
<tr>
<td>Advanced Concepts in Diagnostic Imaging*</td>
</tr>
<tr>
<td><strong>MANAGEMENT PROGRAMS</strong></td>
</tr>
<tr>
<td>Medical Management</td>
</tr>
<tr>
<td>Management Contract</td>
</tr>
<tr>
<td>Medical Laboratory Management for Diagnostic</td>
</tr>
<tr>
<td>Accuracy and Cost Containment</td>
</tr>
<tr>
<td><strong>DENTAL PROGRAM</strong></td>
</tr>
<tr>
<td>Radiological Techniques in Dentistry</td>
</tr>
</tbody>
</table>

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Technetium Tc 99m Aggregated Albumin Kit

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Indications and usage
Technetium Tc 99m Aggregated Albumin is indicated as a lung imaging agent to be used as an adjunct in the evaluation of pulmonary perfusion.

Contraindications
Technetium Tc 99m Aggregated Albumin should not be administered to patients with severe pulmonary hypertension.

The use of Technetium Tc 99m Aggregated Albumin is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

Warnings
The possibility of allergic reactions should be considered in patients who receive multiple doses.

Theoretically the intravenous administration of any particulate material such as aggregated albumin imposes a temporary small mechanical impediment to blood flow. While this effect is probably physiologically insignificant in most patients, the administration of aggregated albumin is possibly hazardous in acute cor pulmonale and other states of severely impaired pulmonary blood flow.

This radiopharmaceutical preparation should not be administered to children, to pregnant women or lactating women unless the expected benefits to be gained outweigh the potential risks.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Precautions
In cases of right-to-left cardiac shunt, additional risk may exist due to the rapid entry of aggregated albumin into the systemic circulation.

The contents of the kit are not radioactive. However, after the Sodium Pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained.

The labeling reactions involved in preparing the agent depend on maintaining the tin in the reduced state. Any oxidant present in the Sodium Pertechnetate Tc 99m supply may thus adversely affect the quality of the prepared agent. Hence, Sodium Pertechnetate Tc 99m containing oxidants, or other additives, should not be employed without first demonstrating that it is without adverse effect on the properties of the resulting agent.

The contents of the vial are sterile and pyrogen-free. It is essential that the user follows the directions carefully and adheres to strict aseptic procedures during preparation of the radiodiagnostic.

Technetium Tc 99m Aggregated Albumin is physically unstable and as such the particles will settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactivity.

It is also recommended that, because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m Aggregated Albumin not be used after eight hours from the time of preparation. Refrigerate at 2° to 8°C after preparation. If blood is withdrawn into the syringe, unnecessary delay prior to injection may result in clot formation in situ.

The contents of the vial are under a nitrogen atmosphere and should be protected from air. On preparation with Sodium Pertechnetate Tc 99m, the contents of the vial should be mixed by gentle swirling to avoid changes in particle size. Do not use if clumping or foaming of the contents is observed.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Aggregated Albumin should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Safety and effectiveness in children have not been established.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to the occupational worker.

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 governmental agency authorized to license the use of radionuclides.

Adverse reactions
The literature contains reports of deaths occurring after the administration of aggregated albumin to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc 99m labeled aggregated albumin have been reported.

Hypersensitivity reactions are possible whenever protein-containing materials such as Technetium Tc 99m labeled aggregated albumin are used in man. Epinephrine, antihistamines and corticosteroid agents should be available for use.

How supplied

5 STERILE MULTIDOSE REACTION VIALS (10 cc, silver aluminum seal), each containing 0.34 mg MAA Aggregated Normal Serum Albumin (Human) 2.0 x 10²± 25% particles, 0.27 mg stannous tartrate, 0.6 ml of isotonic saline. Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment.

10 PRESSURE-SENSITIVE LABELS for final Technetium Tc 99m Aggregated Albumin preparation.

1 PACKAGE INSERT.

Lead shield available, Catalog No. 17500502.

FOR FULL PREPARATION AND PRESCRIBING INFORMATION, SEE PACKAGE INSERT.

Notes:
PHYSICIAN, Nuclear Medicine, Board eligible/certified with Nuclear Medicine experience preferred. Contact: Raymond B. Gentile, M.D., Chief Nuclear Medicine Department. Submit resume to Box 24362, Rochester, NY 14602-3624.

NATIONAL NUCLEAR MEDICINE CONSULTANT. Position open at the Washington, DC headquarters of the American College of Nuclear Physicians. Contact: Peter L. Keating, M.D., American College of Nuclear Physicians, 1100 Seventeenth St. NW, Washington, DC 20036. Submit resume to: PLACEMENT, JOURNAL OF NUCLEAR MEDICINE, Suite 100, 530 W. Fullerton Avenue, Chicago, IL 60614-3696.

NURSE ANESTHETIST. United Healthcare, Inc. is recruiting for a Nurse Anesthetist position. Submit resume to: Nutricia, Inc., Att.: Joyce Smith, PO Box 1149, Darien, IL 60561-1149.

NURSE — Head Nurse. University of Wisconsin at Madison. Please contact: Dr. John E. Convery, Department of Radiation Therapy, University of Wisconsin, Madison, WI 53792. Please include: name, address, phone number, and a letter detailing why you are interested in this position.

NUCLEAR MEDICINE RESIDENCY. Two year program in Nuclear Medicine with two positions available. For more information, contact: Department of Radiology, New York University Medical Center, 465 East 72nd Street, Room 621, New York, NY 10021. Submit resume to: Paul A. Langer, M.D., Professor and Chairman, Department of Radiology, New York University Medical Center, 535 East 68th Street, New York, NY 10021.

NUCLEAR PHYSICIST. The United States Department of Energy has a new opening in the field of nuclear physics. Contact: John R. Haggerty, Assistant Director, Nuclear Physics Program, Oak Ridge National Laboratory, P.O. Box 20088, Oak Ridge, TN 37830.

NUCLEAR PHYSICIST—ABNM Board Certified. Full-time position in Nuclear Medicine at the University of California, Los Angeles. Contact: D. K. Stone, M.D., Department of Radiology, University of California, Los Angeles, CA 90024. Submit resume to: D. K. Stone, M.D., Department of Radiology, University of California, Los Angeles, CA 90024.

NUCLEAR PHYSICISTS. The University of California, San Francisco, has a new opening for two Nuclear Physicists. Contact: Judith S. Goldsmith, M.D., Department of Radiology, University of California, San Francisco, CA 94143. Submit resume to: Judith S. Goldsmith, M.D., Department of Radiology, University of California, San Francisco, CA 94143.

NUCLEAR PHYSICISTS. The University of Wisconsin at Madison has a new opening for a Nuclear Physicist. Contact: Antone R. Smith, M.D., Department of Radiology, University of Wisconsin, Madison, WI 53792. Submit resume to: Antone R. Smith, M.D., Department of Radiology, University of Wisconsin, Madison, WI 53792.

PHARMACY DOCTOR. A one year residency position in Nuclear Medicine at the University of Michigan is available. Contact: Dr. Charles A. Bierman, Department of Radiology, University of Michigan, Ann Arbor, MI 48109.

PHYSICIAN, Nuclear Medicine. Full-time opening available in Nuclear Medicine at the University of California, San Diego. Contact: Dr. David B. Hannon, Department of Radiology, University of California, San Diego, CA 92103. Submit resume to: Dr. David B. Hannon, Department of Radiology, University of California, San Diego, CA 92103.

PLACEMENT POSITIONS OPEN

NUCLEAR MEDICINE RESIDENCY. Two years training in Nuclear Medicine with two positions available. For more information, contact: Department of Radiology, New York University Medical Center, 465 East 72nd Street, Room 621, New York, NY 10021. Submit resume to: Paul A. Langer, M.D., Professor and Chairman, Department of Radiology, New York University Medical Center, 535 East 68th Street, New York, NY 10021.

PHYSICIAN, Nuclear Medicine. State Univ. of New York at Buffalo has two openings at the Atst./Assoc. Prof. level. New York University Medical Center, 535 East 68th Street, New York, NY 10021. Contact: Dr. Robert A. Langer, M.D., Chief of Nuclear Medicine, University of Buffalo Medical Center, Buffalo, NY 14215.

PHYSICIAN. University of California, Los Angeles, has a new opening for a Nuclear Physicist. Contact: Dr. Robert A. Langer, M.D., Chief of Nuclear Medicine, University of Buffalo Medical Center, Buffalo, NY 14215.
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An integrated program at State University of New York at Buffalo School of Medicine. Available July 1, 1979. Contact: M.A. Bender, M.D., Program Director, Dept. of Nuclear Medicine, 666 Elm Street, Buffalo, NY 14263 or M. Blau, Ph.D., Chairman, Dept. of Nuclear, 3495 Bailey Avenue, Buffalo, NY 14215.
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Requests for further information should be directed to John A. Burdine, M.D., Chief, Nuclear Medicine Section, or Paul H. Murphy, Ph.D., Residency and Fellowship Coordinator, Department of Radiology, Baylor College of Medicine, Houston, Texas 77030.
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See next page for brief summary.
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INDICATIONS AND USAGE: Sodium pertechnetate 99mTc is indicated for brain imaging, thyroid imaging, salivary gland imaging, blood pool imaging, and placenta localization.

CONTRAINDICATIONS: None known.

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Since 99mTc is excreted in human milk during lactation, formula-feedings should be substituted for breast-feedings.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

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.

IMPORTANT: Since material obtained from the generator may be intended for intravenous administration, aseptic technique must be strictly observed in all handling. Only the eluent provided should be used to elute the generator. Do not administer material eluted from the generator if there is any evidence of foreign matter.

PRECAUTIONS: In the use of any radioactive material, care should be taken to insure minimum radiation exposure to the patient and occupational workers consistent with proper patient management. At the time of administration the solution should be crystal clear.

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*ALUMINUM BREAKTHRU KIT C 404 For the determination of aluminum ion concentration in Tc-99m pertechnetate eluate.

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Delivery module is mounted over gas trap. Two handle control system channels gas and air through each phase of all regional ventilation studies.

#130-330 Xenon Delivery Unit
#127-313 Xenon Gas Trap

Only $1890.
The superior technique: "The bone scan may be the only technique capable of locating sites of suspected or unsuspected (bone) trauma." 


The superior agent: 

OSTEOLITE™

Technetium Tc 99m Medronate Sodium Kit (MDP)

New England Nuclear®
In bone trauma...when the X-ray is inconclusive.

Most rapid blood clearance

- At 90 minutes postinjection, blood clearance of MDP pharmacologically identical to OSTEOLITE was approximately equal to that of tested pyrophosphate agents at 6 hours postinjection.
- At 3 hours, MDP blood levels were considerably less than those of tested EHDP and pyrophosphate.

**Result:** low-background studies, whether you must scan early to meet patient-flow demands, or at 3 hours for more optimal image detail.

Lowest soft tissue activity

The "difference in soft tissue activity (highest with polyphosphate and lowest with MDP) is discernible in clinical images." A University of Minnesota study found that only 4% of 175 MDP images showed moderate to marked soft tissue activity, compared to 17% of EHDP images.

**Result:** highest assurance of visualizing all skeletal structures.

Highest target-to-background differential

OSTEOLITE's rapid blood clearance and lower soft tissue uptake usually enable current gamma cameras to resolve peripheral skeletal structures and phalanges.

**Result:** confidence of detecting resolution-challenging alterations in osteogenesis...even roentgenographically "invisible" fractures and small metastases.

Convenient storage and preparation

Available in 5-vial or 30-vial "Convenience Packs," OSTEOLITE can be stored and used at room temperature (15–30°C).

REFERENCES:
3. Forstrom L et al: Data on file at New England Nuclear, Medical Diagnostics Division, North Billerica, MA
A 23-year-old graduate student actively engaged in amateur soccer complained of pain in both knees. X-rays of both knees suggested the possibility of a stress fracture only at the right proximal tibia. OSTEOLITE images of the right knee displayed focal uptake in the proximal tibia, consistent with the diagnosis of a stress fracture. A routine anterior view of both knees disclosed a roentgenographically occult stress fracture of the left proximal tibia as well.

Images produced with 19.6 mCi technetium-99m labeled OSTEOLITE; recorded at 500 K counts, Searle LFOV™ camera with Micro Dot™ Imager.
Technetium Tc 99m decayed by isometric transition with a physical half-life of 6.02 hours. SOURCCE: Martin, J. M. Nuclear Data Project. Oak Ridge National Laboratory, March, 1976.) Photons that are useful for imaging studies are listed in Table 1.

### Table 1. Principal Radiation Emission Data—Technetium Tc 99m

<table>
<thead>
<tr>
<th>Mean %</th>
<th>Mean Energy (keV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-2</td>
<td>88.96</td>
</tr>
</tbody>
</table>

To facilitate correction for physical decay of Technetium Tc 99m, the fractions of initial activity that remain at selected intervals after the time of calibration are shown in Table 2.

### Table 2. Physical Decay Chart—Technetium Tc 99m Half-Life 6.02 Hours

<table>
<thead>
<tr>
<th>Fraction Remaining</th>
<th>Hours</th>
<th>Fraction Remaining</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.89</td>
<td>8</td>
<td>0.36</td>
<td>3</td>
</tr>
<tr>
<td>0.89</td>
<td>10</td>
<td>0.36</td>
<td>6</td>
</tr>
<tr>
<td>0.89</td>
<td>11</td>
<td>0.36</td>
<td>9</td>
</tr>
<tr>
<td>0.89</td>
<td>12</td>
<td>0.36</td>
<td>12</td>
</tr>
<tr>
<td>0.89</td>
<td>18</td>
<td>0.36</td>
<td>24</td>
</tr>
<tr>
<td>0.89</td>
<td>24</td>
<td>0.36</td>
<td>36</td>
</tr>
</tbody>
</table>

*Calibration Time*

**EXTERNAL RADIATION**

The specific gamma ray constant for Technetium Tc 99m is 0.89 mCi/μCi·hr. at 1cm. The half value layer is 0.2mm of Pb. To facilitate control of radiation exposure from micromicrocuries of Technetium Tc 99m, the use of a 0.63mm thick standard radiation elution lead shield will attenuate the radiation emitted by a factor greater than 10.

### Table 3. Radiation Attenuation By Lead Shielding

<table>
<thead>
<tr>
<th>Shield Thickness (Pbmm)</th>
<th>Coefficient of Attenuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>0.95</td>
<td>1.0</td>
</tr>
<tr>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>2.0</td>
<td>1.0</td>
</tr>
<tr>
<td>3.6</td>
<td>1.0</td>
</tr>
<tr>
<td>4.5</td>
<td>1.0</td>
</tr>
<tr>
<td>5.4</td>
<td>1.0</td>
</tr>
<tr>
<td>6.3</td>
<td>1.0</td>
</tr>
</tbody>
</table>

**CLINICAL PHARMACOLOGY**

Upon intravenous injection, Technetium Tc 99m OSTEOLITE exhibits a specific affinity for areas of altered osteogenesis. In humans, blood levels fall to 4-10% of the injected dose by two hours post-injection and to 3-5% by three hours. During the first 24 hours following its administration in patients with normal renal function, 50-75% of the radioactivity is excreted into the urine and less than 2% of the injected dose remains in the vascular system.

The uptake of the Technetium Tc 99m in bone appears to be related to osteogenic activity and to skeletal blood perfusion. The deposition in the skeleton is bilaterally symmetrical, with increased accumulation in the axial structure as compared to the appendicular skeleton. There is increased activity in the distal aspect of long bones as compared to the diaphyses. In pediatrics, in whom the epiphyseal centers are still open, there is more marked accumulation of the radiopharmaceutical in the distal aspects of long bones than is seen in adults in whom the epiphyseal centers are closed. Localized areas of abnormal accumulation of the radiopharmaceutical may be seen in primary skeletal malignancies, metastatic malignancies to bone, acute or chronic osteomyelitis, arthritides, recent fractures, areas of ectopic calcification. Paget's disease, regional migratory osteoporosis, areas of aseptic necrosis and, in general, any pathological situation involving bone in which there is increased osteogenic activity or localized increased osseous blood perfusion. Since increased osteogenic activity and localized increased osseous blood perfusion are not usually present in chronic bone diseases, bone imaging agents, in general, are not effective in detecting such diseases. Localized areas of decreased accumulation of the radiopharmaceutical may be noted in areas of bone which have received localized fields of external radiation or to which blood flow has been interrupted. OSTEOLITE has also been noted to accumulate in areas of acute myocaridal infarction from one to fourteen days after the pathologic event.

**INDICATIONS AND USAGE**

Technetium Tc 99m OSTEOLITE may be used as a bone imaging agent to delineate areas of altered osteogenesis.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

The contents of the OSTEOLITE vial are intended only for use in the preparation of Technetium Tc 99m medronate sodium and are NOT to be directly administered to the patient.

Ideally, examinations using radiopharmaceuticals—especially those elective in nature—of children with chickling capability should be performed during the first ten days following the onset of menarche.

**PRECAUTIONS**

A thorough knowledge of the normal distribution of intravenously administered Technetium Tc 99m medronate sodium is essential in order to accurately interpret pathologic studies. Technetium Tc 99m medronate sodium, as well as any radiopharmaceutical, must be handled with care. Once sodium pertechnetate Tc 99m is added to the kit, appropriate safety measures should be used to minimize external radiation exposure to personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

Technetium Tc 99m labeling reaction involved in preparing Technetium Tc 99m medronate sodium depends on the maintenance of tin in the divalent state. Any oxide present in the sodium pertechnetate Tc 99m employed may adversely affect the quality of the prepared agent. Thus, sodium pertechnetate Tc 99m containing oxidants should not be used without first demonstrating that it is without adverse effect on the properties of the resulting agent.

The use of bacteriostatic sodium chloride as a diluent for sodium pertechnetate Tc 99m may adversely affect the biologic distribution of the prepared agent, and its use is not recommended.

Adenquate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m medronate sodium should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule nursing should not be undertaken when a patient is administered radioactive material.

**ADVERSE REACTIONS**

None reported.

**DOSAGE AND ADMINISTRATION**

The recommended dose for the average 70kg adult patient is 15mCi with a range of 10-20mCi. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Optimal imaging results are obtained within one to four hours after administration.

OSTEOLITE should be used within six hours after aseptic reconstitution with sodium pertechnetate Tc 99m. For optimum results this time should be minimized.

The vial contains no bacteriostat. Radiopharmaceuticals should be used by persons who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agencies authorized to license the use of radionuclides.

**RADIATION DOSIMETRY**

The estimated absorbed radiation dose to an average patient (70kg) from an intravenous injection of a maximum dose of 20 millicuries of Technetium Tc 99m OSTEOLITE is shown in Table 4.

### Table 4. Absorbed Radiation Dose—Technetium Tc 99m Medronate Sodium

<table>
<thead>
<tr>
<th>Organ</th>
<th>(rads/20mCi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body</td>
<td>0.13</td>
</tr>
<tr>
<td>Bone Total</td>
<td>0.70</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.56</td>
</tr>
<tr>
<td>Kidneys</td>
<td>0.62</td>
</tr>
<tr>
<td>Liver</td>
<td>0.16</td>
</tr>
<tr>
<td>Bladder Wall</td>
<td>2.60</td>
</tr>
<tr>
<td>2 hr v/d</td>
<td>6.20</td>
</tr>
<tr>
<td>4.8 hr</td>
<td>3.34</td>
</tr>
<tr>
<td>6 hr</td>
<td>0.24</td>
</tr>
<tr>
<td>Ovaries</td>
<td>0.16</td>
</tr>
<tr>
<td>2 hr v/d</td>
<td>0.34</td>
</tr>
<tr>
<td>Tests</td>
<td>4.8 hr v/d</td>
</tr>
</tbody>
</table>


**HOW SUPPLIED**

NEN's OSTEOLITE Technetium Tc 99m Medronate Sodium Kit is supplied as a set of five or thirty vials, sterile and non-pyrogenic. Each nitrogen-flushed vial contains in hyphosphorized form: Medronate Disodium—10mg, Stannous Chloride Dihydrate—0.85mg.

The pH is adjusted to between 7.0-7.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial were hyphosphorized under nitrogen. Store at room temperature (15°-30° C). Included in each five (5) vial kit is one (1) package insert and six (6) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels.

**INSTRUCTIONS FOR PREPARATION OF TECHNETIUM Tc 99m OSTEOLITE**

Bacteriostatically inject 2 to 8ml of sodium pertechnetate Tc 99m (pertechnetate in isotonic saline without a bacterio- stat) into the supplied vial of OSTEOLITE enclosed by a radiation shield. Swirl for at least ten seconds to dissolve completely. Label appropriately. Suitable labels have been supplied with each OSTEOLITE Kit. Use within six hours after reconstituti. For optimum results, this time should be minimized.

Using proper shielding, the vial containing the reconstituted solution should be visually inspected to insure that it is clear and free of particulate matter.

The contents of the kit vials are not radioactive, however, after reconstitution with sodium pertechnetate Tc 99m the contents are radioactive and adequate shielding and handling precautions must be maintained.

Do not use if there is a vacuum in the immediate drug container or if air is injected into the container when the dose is withdrawn.

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| SI-23  | Instrumentation for Nuclear Cardiology: Trevor D. Craddock |
| SI-24  | Your Nuclear Medicine Examination: An Audiovisual for Patients (*) |

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<thead>
<tr>
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<th>SI-14</th>
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<tr>
<td></td>
<td>SI-15</td>
<td>SI-23</td>
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<tr>
<td></td>
<td>SI-18</td>
<td>SI-24</td>
</tr>
<tr>
<td></td>
<td>SI-21</td>
<td></td>
</tr>
</tbody>
</table>

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