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

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

DESCRIPTION: The Xenon Xe 133-Ventilation Study System (V.S.S.) consists of a sealed plastic tube containing 10 millicuries ±20% of Xenon 133 gas at calibration time and date with less than 1% carrier Xenon in air.

INDICATIONS AND USAGE: Study of pulmonary ventilation.

CONTRAINDICATIONS: None known.

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 effective 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 133-V.S.S. (VENTILATION STUDY SYSTEM) Xenon Xe 133 diagnostic

True, single-unit dose
The MPI Xenon 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.

Reduced radiation exposure
The xenon Xe 133 is supplied in a sealed plastic container. 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 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 the 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 133 in a sealed plastic tube containing 10 millicuries ±20% at calibration time and date stated on the label.

The sealed plastic tube is enclosed in a metal valve-shield which is sealed with a plastic shrink band to prevent accidental loss of Xenon 133 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 plastic tube. The V.S.S. also includes a disposable mouthpiece and a breathing-collection bag with an attached CO₂ absorber canister.

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In West Germany: Amersham Buchler GmbH & Co KG, Braunschweig. Tel: 05307-4693-97
Abington Memorial chose a camera for maximum image quality and convenience.

The 520-bed Abington Memorial Hospital in Abington, PA, outside Philadelphia, has added a new Raytheon XL-91 gamma camera to its new wing. And right from start-up the XL-91 has been producing images of superior resolution, with much greater patient accessibility and operator convenience than other equipment.

The reasons for the XL-91’s success at Abington are clear. At 16½ inches the XL-91 provides the widest undistorted field of view of any gamma camera. The XL-91’s exclusive Autocomp circuitry achieves ±2% uniformity and — with as many as four memories — permits users to calibrate to four different isotopes or collimators.

Patient comfort, operator convenience, superior high resolution images. No wonder Abington Memorial had the XL-91 working a full patient schedule just days after delivery. And outstanding customer acceptance of the XL-91 — such as at Abington Memorial — is the reason Raytheon has had to expand its sales and service coverage greatly. From coast to coast, wherever you are, Raytheon is now near you.

If you’d like more information on the XL-91, write or phone Raytheon Company, Medical Electronics, 70 Ryan Street, Stamford, CT 06907. Telephone: 800-243-9058. We will put you in touch with your nearest Raytheon sales engineer.

The Raytheon XL-91...the 91-tube image maker.
A distinguished family.

New England Nuclear
Radiopharmaceutical Division

Atomlight Place, North Billerica, Mass. 01862
Telephone: 617-667-9531
Los Angeles: 213-321-3311
The powder
the picture

The label

99mTc SOLCO® HIDA

Lyophilized labeling kit for the preparation of 99mTc-diethyl-IDA* for radionuclide studies of the hepatobiliary system.

*N (2,6-diethylacetoanilido) iminodiacetic acid

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Kodak's experience in making quality products for photographic and radiographic images goes back many years. And today, that same expertise and technology is being applied to the new diagnostic modalities. The result is a combination of high image quality with speed, efficiency, and economical performance.

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For more information, contact your x-ray products dealer. Or write: Eastman Kodak Company, Dept. 740-B, Rochester, New York 14650.

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We’re serious.

Ask any doctor who uses the ADAC Clinical Data System what he thinks of it.

He’s likely to tell you it’s the finest system in nuclear medicine today for quantitative organ function analysis.

We’ve had doctors call us voluntarily to tell us that.

What are the reasons for this enthusiasm? They are plain to see.

Only ADAC delivers an image of such high resolution—the result of our exclusive 512 x 512 display format and 64 shades of gray. You get an image that is nearly identical to original analog scintiphotos.

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To arrange for a demonstration at a convenient location near you, please write or phone collect.


Phone: (408) 736-1101.
Mallinckrodt research has now developed a formula that combines the quality features of our frozen TechneScan MAA product with the convenience of lyophilization. Our goal was to match—as closely as possible—particle-size range and consistency specifications that had been established with the frozen process. In our search we were determined not to compromise current product performance or specifications of our frozen product for the sake of convenience.

The introduction of Mallinckrodt's TechneScan MAA—Lyophilized—represents the successful conclusion of our search for a specially designed freeze dry process. No need to freeze. Simply refrigerate for these same quality features.

**Safety . . .**
TechneScan MAA is very well tolerated. Effective lung excretion half-life is approximately 3.8 hours—virtually complete biological excretion occurs in about 24 to 48 hours. Although the possibility exists, there is, to date, no evidence of antibody formation.

**Increased Shelf Life . . .**
The expiration date of each TechneScan MAA lyophilized kit is now one year after date of manufacture. This extended shelf life permits the convenience of larger inventories plus the cost savings of buying in quantity.

**Reliable Consistency . . .**
Reconstitution does not affect either particle quality or size distribution. The particle size does not change after the addition of pertechnetate solution. There is no tendency for the particles to hydrate and increase in size after labeling. WE ENCOURAGE MICROSCOPIC EVALUATION AND COMPARISON!

**Controlled Particle-Size Range . . .**
Specifications require that not less than 90% of the particles be 10 to 90 microns in size, with not more than 10% below 10 microns, and none greater than 150 microns. Our investigations indicate that, typically, 90% of the TechneScan MAA particles are in the 10-40 microns range. This controlled particle size range, plus the fact that there is no tendency to agglomerate, results in good images of lung perfusion.

**High Tagging Efficiency . . .**
The tagging efficiency experienced with the TechneScan MAA kit is remarkably consistent, always at or near 100% conversion of pertechnetate to labeled MAA, with no loss of the label for up to 24 hours.

**Easy Preparation . . .**
Preparation of TechneScan MAA Tc 99m is easy:
1. Allow five minutes to reach room temperature.
2. Add Tc-99m.
3. Agitate gently.
4. Wait fifteen minutes for high tagging efficiency.
That's all!!

**Economy . . .**
The TechneScan MAA Kit doesn't need expensive accessory equipment. Up to 15 adult patients can be scintigraphed from the preparation of a single vial of TechneScan MAA. This helps reduce the procedure cost per patient. For those who were acquainted with the frozen product, we give our assurance of continued satisfaction; for those who were unable to use frozen TechneScan MAA because of storage considerations, we invite your evaluation of our lyophilized formula. For further information contact your Mallinckrodt representative.

**LYOPHILIZED**
TechneScan® MAA
(AGGREGATED ALBUMIN (HUMAN))
LUNG SCAN KIT

Consult package insert for complete prescribing information, a summary of which follows the next page.
TechneScan® MAA KIT

AGGREGATED ALBUMIN (HUMAN) KIT (Lyophilized)
Catalog No. 093

Store at 2°C – 8°C
The ice is out at Mallinckrodt.
The qualities you liked in our frozen product are all here in its lyophilized successor.

TechneScan MAA Lyophilized
(Aggregated Albumin (Human))

Multi-Dose Kit for the Preparation of Technetated (Tc 99m) Aggregated Albumin (Human)

Diagnostic—For Intravenous Use

Description—For Intravenous Use

The TechneScan MAA 10-milliliter vial contains a sterile, pyrogen-free, lyophilized mixture of 2.0 milligrams of aggregated albumin (Human), 120 micrograms of stannous chloride dihydrate, 80 milligrams of lactose, 24 milligrams of succinic acid and 1.4 milligrams of sodium acetate. TechneScan MAA is prepared from albumin that was nonreactive when tested for hepatitis B antigen (HBsAg) by radioimmunoassay. Each vial contains approximately $8 \pm 2 \times 10^{9}$ aggregated albumin particles. The particle size distribution of the aggregated albumin is such that not less than 90 percent are 10 to 90 microns in size. Typically, approximately 90 percent are within the 10 to 40 micron range. There are no aggregated albumin particles greater than 150 microns in size. Reconjugated TechneScan MAA with sterile, non-lyophilized sodium per technetate Tc-99m provides an aqueous suspension of technetium Tc-99m aggregated albumin, with a labeling efficiency of 90 percent or greater.

Indications and Usage

TechneScan MAA Tc 99m is indicated only for scintigraphic imaging of the lungs as an adjunct to other diagnostic procedures whenever information about pulmonary circulation is desired.

Contraindications

The use of TechneScan MAA Tc 99m is contraindicated in patients 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 of TechneScan MAA Tc 99m.

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 cardiac or pulmonary and other states of severely impaired pulmonary blood flow. This radiopharmaceutical preparation should not be administered to patients under the age of 18, to pregnant women or to nursing mothers unless the expected benefits to be gained outweigh the potential risks.

Ideally, examination using radiopharmaceuticals, especially those effective in nature, of women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menstruation.

Precautions

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

The contents of the TechneScan MAA 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 TechneScan MAA Tc 99m depend upon maintaining tin in the reduced state. Any oxidants present in the sodium pertechnetate Tc 99m may thus adversely affect the quality of the preparation. Hence, sodium pertechnetate Tc 99m containing oxidizing agents is not suitable for preparation of TechneScan MAA Tc 99m.

The contents of the TechneScan MAA vial are sterile and pyrogen free. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiopharmaceutical.

TechneScan MAA Tc 99m is a suspension and as such the particles settle with time. Failure to mix the vial contents adequately before use may result in a non-homogenous suspension with a resulting non-uniform distribution of radioactivity in the lung.

It is also recommended that, because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m aggregated albumin will 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, unnecessary delay prior to injection may result in c formation in situ.

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

Adverse reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, its 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 similar 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 management and to ensure minimum radiation exposure to occupational workers.

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 idiiosyncratic reactions to preparations of Tc 99m-labeled aggregated albumin having been reported.

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

Dosage and Administration

The recommended intravenous dose range for the average patient (70 kg) is 1 to 4 microliters. The volume of the dose may vary from 1 to 10 ml.

The recommended number of aggregated albumin particles to be administered per dose is 200,000-1,200,000 with the suggested number being approximately 600,000.

How Supplied

Catalog Number 093 TechneScan MAA Kit (Lyophilized)

Kit Contains:

5—Aggregated Albumin (Human) Reaction Vials (1 ml each)—for the preparation of Technetated (To-99m) Aggregated Albumin (Human)

Reaction Vial Contains (in lyophilized form):

2.0 mg Aggregated Albumin (Human) (8 ± 2 x 10^9 particles)
120 µg Stannous Chloride Dihydrate
30 mg Lactose
24 mg Succinic Acid
1.4 mg Sodium Acetate
500 µg Hydrochloric Acid or Sodium Hydroxide is added for pH adjustment.

Each vial contains 8 ± 2 x 10^9 aggregated albumin particles.

TechneScan MAA contains no preservatives; after reconstitution, shielded vial should be stored at 2° to 8°C.

Included in each package is one (1) package insert, 5 radiation and 5 radioassay information string tags.
thrombosis
detection of DVT using I-125 fibrinogen

- Direct digital percent readout
- Printout saves time
- Bedside operation
- Right angle probe minimizes patient disturbance
- Controls are on probe
- Operator error protection
- Versatile — settable for other isotopes

**Print Out**
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Real time diagnostics at a realistic price.
Computing cardiac ejection fraction is a vital job. But, it's also an expensive and complicated one. Most hospitals cannot afford the luxury of a nuclear medicine system and the computer-trained personnel required to accomplish this time-consuming technical task. But, they can afford the efficiency of a Picker Nuclear Cardiology Module, which can quickly determine ejection fraction at a fraction of the cost of a computer.

Complex cardiac assignments, simply performed. Picker's new Cardiac Module, the first of its kind in the marketplace, is an easy, uncomplicated way to produce meaningful left ventricular function data. Now, without the services of a computer-trained technologist, you can obtain instant on-line, 30-second sequential ejection fraction, indicated on an LED display, with corroborative hard copy strip chart recordings. The Picker Cardiac Module, used with our Dyna® Camera, will
Opening a new world for nuclear medicine. Our new Cardiac Module means the radiologist can now provide prophylactic nuclear medicine. He can screen patients prior to surgery with real-time results in 30 seconds, at a reasonable cost to hospital and patient. He can help forestall problems arising from insufficient pre-operative input and provide significant postoperative patient management. He can begin to minimize the need for cardiac catheterization. The Picker Cardiac Module: another indication of Picker's leadership in supplying state-of-the-art equipment for Nuclear Cardiology. For additional information, contact your Picker representative, write Picker Corporation, 12 Clintonville Road, Northford, CT 06472 (203/484-2711), or Picker International, 595 Miner Road, Cleveland, OH 44143.
Dependable bone
lesion detection

PROCTER & GAMBLE

OSTEOSCAN®
(5.9MG DISODIUM ETIDRONATE, 0.16MG STANNOUS CHLORIDE)
SKELETAL IMAGING AGENT

Excellent in vitro stability
Greater than 98% labeling efficiency 8 hours after preparation. Osteoscan contains sodium ascorbate, an antioxidant that inhibits action of radiolysis by-products and oxidants capable of causing complex breakdown and resultant soft tissue visualization.

Compatible with all types of technetium
Delivers consistently high-quality scans, using either instant or generator technetium.

Plus these other Osteoscan benefits
- very low tin level to minimize potential for liver visualization and for interference with subsequent brain scans
- rapid blood clearance
- high target-to-nontarget ratio
- diphosphonate’s P-C-P bond for excellent in vivo stability

For further information about Osteoscan, please contact: Arnold Austin, Technical Manager, Professional Services Division, Procter & Gamble (513) 977-8547.

In Europe, contact: Philips-Duphar B.V., Cyclotron and Isotope Laboratories, Petten, Holland.
See following page for a brief summary of package insert.
SETHOTOPE®
Selenomethionine Se 75 Injection

Sethotope (Selenomethionine Se 75 Injection) is a sterile, nonpyrogenic, aqueous solution of L-selenomethionine providing a specific activity of not less than 25 microcuries per mcg. of selenium at the time of manufacture. The product also contains, in each ml., not more than 3 mg. L-methionine as a carrier, not more than 1.5 mg. 2-aminoethanethiol as an antioxidant, sodium chloride for isotonicity, and 0.9% (w/v) benzyl alcohol as a preservative.

CONTRAINDICATIONS: At present, there are no known contraindications to the use of Selenomethionine Se 75 Injection.

WARNINGS: Radiopharmaceuticals should not be administered to patients who are pregnant or to nursing mothers unless the information to be gained outweighs the potential hazards.

The placental transport and long biologic half-time of this agent may result in significant radiation exposure to the fetus. Since selenomethionine 75Se 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.

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.

Fasting prior to administration may enhance the hepatic uptake of the agent which may result in degradation of pancreatic image quality.

ADVERSE REACTIONS: At present, adverse reactions have not been reported following administration of Selenomethionine Se 75 Injection.

For full prescribing information, consult package insert.

HOW SUPPLIED: Sethotope (Selenomethionine Se 75 Injection) is available in multiple dose vials in potencies of 0.25 millicurie, 0.5 millicurie, and 1 millicurie. Complete assay data for each vial are provided on the container.

E. R. Squibb & Sons, Inc.
P.O. Box 4000
Princeton, N.J. 08540

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High pancreas specificity

Selenomethionine is a structural analog of the amino acid, methionine, in which the selenium has been substituted for the sulfur atom. Chemically and biologically, they behave alike, including a relatively high degree of uptake in the pancreas during protein synthesis.

Levorotatory compound

Radioactive selenomethionine can be produced in racemic form by chemical synthesis from $^{75}\text{Se}$. At Squibb, however, selenomethionine is prepared biosynthetically by extracting it from the protein product of yeast grown on a low sulfur medium containing $^{75}\text{Se}$ of high specific activity. This compound is levorotatory.

Specific activity

Squibb L-selenomethionine $^{75}\text{Se}$ provides a specific activity of not less than 25 microcuries per microgram of selenium at the time of manufacture.

Sethotope®
Selenomethionine Se 75 Injection

See opposite page for brief summary.
Early detection of deep vein thrombosis of the legs can be accomplished using I-125 labelled fibrinogen and the Model 145A. The leg is scanned after intravenous injection of the labelled fibrinogen. As a thrombosis develops, the radio-active fibrinogen is detected at predetermined points and measured directly as a percentage of the pre-cardial count.

Handily compact and portable, with standard D cell battery operation providing at least 100 hours of uncycled use, the 145A Localization Monitor offers unlimited isotope selection, stainless steel collimator, and solid state design.

Early detection of Deep Vein Thrombosis
Mum
dose
Technetium
Tc 99m
Human Serum Albumin
Reagent
Kit
Five sterile multidose reaction vials each containing 21 mg human serum albumin and 0.23 mg stannous tartrate, lyophilized. Hydrochloric acid was added prior to lyophilization for pH adjustment.

REAGENT KIT FOR CARDIAC BLOOD POOL IMAGING

Maximum vial activity 100 mCi/3 ml

Easy to prepare (see directions): Just add sterile preservative-free water, Technetium 99m pertechnetate, then shake. Requires no electrolytic equipment or time-consuming procedures.

High blood concentrations: Approximately 60% remains in the circulation after 2 hours, approximately 45% after 4 hours (in normal patients).

Consistently high binding efficiency: Technetium binding range of 90-99% immediately after tagging.

Stable formulation: Uses stannous tartrate, which is more stable to air oxidation than stannous chloride.

Free from extraneous constituents: Following aseptic preparation, final product contains HSA, water, stannous tartrate, and sodium chloride.

For ordering, customer service, and technical information on HSA (Product Number UC-HA-80)
Call toll-free: (800) 431-1146.
In New York State call: (914) 351-2131.

Union Carbide Corporation
Clinical Diagnostics
Nuclear Medicine Products
Tuxedo, New York 10987
techneTium 99m aLLuminiuM aNd RadioactiVe Tc 99m for Intravenous Use

description

The kit consists of 5 multidose reaction vials each containing a labeled mixture of 21 mg human serum albumin and 0.23 mg stannous tartrate. Hydrochloric acid was added prior to lyophilization for pH adjustment. All components are sterile and pyrogen-free. When a solution of sterile and pyrogen-free Sodium Pertechnetate Tc 99m in isotonic saline is mixed with these components, following the instructions provided with the kit, Technetium Tc 99m Human Serum Albumin is formed, with a labeling efficiency of 90% or greater. The product has a pH of 2.5-3.6 and is intended for intravenous injection. The precise structure of Technetium Tc 99m Human Serum Albumin is not known at this time. Two and a half hours after administering Tc 99m Human Serum Albumin used in this preparation was nonreactive when tested for hepatitis B surface antigen (HBsAg) by radioimmunoassay.

physical characteristics

Technetium Tc 99m is available by isometric transition with a physical half-life of 6.03 hours[1]. Photons that are useful for detection and imaging studies are listed in Table I.

1. principal radiation emission data

<table>
<thead>
<tr>
<th>Gamma</th>
<th>Energy (keV)</th>
<th>Intensity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>140.5</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

external radiation

The specific gamma ray constant for Technetium Tc 99m is 0.8 R/milligray-hour at 1 cm. The first half-value thickness of lead (Pb) for Technetium Tc 99m is 0.5 mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table II. For example, the use of 2.7 mm of Pb will decrease the external radiation exposure by a factor of 1,000.

2. radiation attenuation by lead shielding

<table>
<thead>
<tr>
<th>Thickness (Pb) mm</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</td>
</tr>
<tr>
<td>1.8</td>
<td>10</td>
</tr>
<tr>
<td>2.7</td>
<td>10</td>
</tr>
<tr>
<td>3.6</td>
<td>10</td>
</tr>
<tr>
<td>4.5</td>
<td>10</td>
</tr>
</tbody>
</table>

To correct for physical decay of this radionuclide, the fraction of the administered dose remaining in the body at a given time after injection is determined by the following formula:

\[\text{Fraction Remaining} = e^{-\lambda t} \times 100\%\]

where \(\lambda\) is the decay constant and \(t\) is the time in hours.

3. radiation dosage chart:

<table>
<thead>
<tr>
<th>Hours</th>
<th>Fraction Remaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1.000</td>
</tr>
<tr>
<td>1</td>
<td>0.891</td>
</tr>
<tr>
<td>2</td>
<td>0.795</td>
</tr>
<tr>
<td>3</td>
<td>0.708</td>
</tr>
<tr>
<td>4</td>
<td>0.631</td>
</tr>
<tr>
<td>5</td>
<td>0.563</td>
</tr>
<tr>
<td>6</td>
<td>0.502</td>
</tr>
</tbody>
</table>

4. Radiation Dosimetry

The estimated radiation doses to an average patient (70 kg) from intravenous injection of a maximum dose of 5 millicuries of Technetium Tc 99m Human Serum Albumin are shown in Table IV.

clinical pharmacology

Normal Human Serum Albumin, being a normal component of blood, leaves the vascular space at a rate slow enough to permit imaging procedures utilizing radioactive tags. Technetium Tc 99m Human Serum Albumin does not rapidly enter the extravascular spaces, and there is no significant accumulation in organs other than those of excretion, the kidney and bladder. Therefore, the vascular system may be imaged with a minimum of background and organ interference. In humans, a two-component blood clearance rate is observed, the T 1/2 slow component ranging from 10 to 16 hours. Twenty-four hour urine clearance averaged 39%.

indications and use

Technetium Tc 99m Human Serum Albumin is used as an agent for imaging the heart blood pool and to assist in the detection of pericardial effusion and ventricular aneurysm.

contraindications

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

warnings

The contents of the kit are not radioactive. However, after a half-life of 6 hours, Technetium Tc 99m is added, adequate shielding of the final preparation must be maintained. This radiopharmaceutical preparation should not be administered to children or to patients who are pregnant or to nursing mothers unless the expected benefits to be gained outweigh the potential hazards.

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

precautions

The components of the kit 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 Human Serum Albumin must not be used after three hours from the time of formulation. 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 Human Serum 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.

Technetium Tc 99m Human Serum Albumin, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients, consistent with proper patient management.

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 should not be used if any other additives, should not be employed without first demonstrating that it is without adverse effect on the properties of the resulting agent.

adverse reactions

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

dosage and administration

The suggested intravenous dose used in the average patient (70 kg) is 2.5-3.5 millicuries of Technetium Tc 99m Human Serum Albumin.

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

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.

radiation dosimetry

The estimated radiation doses to an average patient (70 kg) from an intravenous injection of a maximum dose of 5 millicuries of Technetium Tc 99m Human Serum Albumin are shown in Table IV.

how supplied

Kit contents:

Store kit contents in refrigerator (2-8°C). Do not freeze.

The residual materials may be discarded in ordinary trash provided the vials and syringes are backlogged with an appropriate low range survey meter. It is suggested that all identifying labels be destroyed before discarding.

directions

The following directions must be carefully followed for optimum preparation of the Technetium Tc 99m Human Serum Albumin.

1. Aseptically swallow rubber septum of sterile vial containing the sterile, lyophilized human serum albumin.

2. Aseptically inject 1.0 ml of Sterile Water for Injection; withdraw an equal volume of air.

3. Mix contents by swirling.

4. Place vial in radiation shield provided.

5. Aseptically swallow rubber septum of shielded vial.

6. Aseptically inject up to 100 millicuries Sodium Pertechnetate Tc 99m in a maximum of 3 ml into the vial; withdraw an equal volume of air.

7. Mix contents of vial by gentle shaking for 10 seconds.

8. Affix pressure-sensitive label to shielded vial.

9. Allow to stand for 20 minutes after mixing to allow maximum tapping.

10. The Technetium 99m HSA is ready for use.

11. Mix contents of vial (step 7) prior to withdraw patient dose.

12. Mix contents of syringe by repeated inversion in prepared vial prior to injection.

13. Maintain adequate shielding of the radiopharmaceutical.

14. Do not use the preparation after 3 hours from the time of formulation.

The radioactivity concentration of the final Technetium Tc 99m Human Serum Albumin preparation may be calculated by using the following formula:

\[A = \frac{C}{V} \times 60 \times 10^6 \text{ mCi/ml} \]

where \(A\) is the activity in mCi/ml, \(C\) is the concentration in microcuries/ml, and \(V\) is the volume of the final mixture (ml).

This kit is approved for use by persons licensed by the U. Nuclear Regulatory Commission pursuant to Sec. 35.14 and Sec. 35.100 Group III of 10 CFR Part 35 or under equivalent license of Agreement States.

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INJECT IBRIN, a Radionuclide-Labeled (¹⁴C) Fibrinogen (Human), is supplied freeze-dried for convenient storage and extended stability. It is reconstituted immediately prior to injection. The patient is intravenously injected with 100µCi of IBRIN prior to testing.

INSPECT Initial monitoring can be performed three hours after the IBRIN injection. The IBRINITOR is specifically designed and built for detecting DVT. Sophisticated electronic design assures reliable accumulation of statistically valid data and eliminates most operator error. The IBRINITOR has a continuous stage design that requires all the correct data in the correct order before giving results. A digital data display and built-in printout insure ease and accuracy of data collection. Push button controls on the detector probe are provided for quick, accurate testing. The probe design includes an angled detector head to facilitate positioning for maximum operator convenience and patient comfort. The IBRINITOR is powered by rechargeable Ni-Cd batteries. A source is provided for calibration convenience and the complete unit weighs less than eight pounds.

DETECT The IBRIN System includes a patient data sheet which provides a convenient display of printout tape and graphical representation of data for the physician’s interpretation and diagnosis.

We will be glad to help you explain the benefits of the IBRIN System to your surgical staff. Write or phone Amersham for complete details.

See following page for brief summary of package insert.
INDICATIONS
IBRIN is indicated for use in prospective studies for the early detection and subsequent monitoring of developing deep-vein thrombosis and in diagnostic studies for the detection of established thrombosis in the legs.

A. The IBRIN (Radionuclide-Labeled (99m) Fibrinogen (Human) test is indicated in patients with signs and/or symptoms suggestive of deep-vein thrombosis with or without associated pulmonary embolism or in patients with pulmonary embolism, with or without evidence of peripheral deep-vein thrombosis. In patients with established, old or "inactive" thrombosis, the test will be positive only if radionuclide-labeled fibrin deposition occurs in a sufficient quantity to allow detection. This use is not contraindicated in patients on anticoagulants.

B. The IBRIN (Radionuclide-Labeled (99m) Fibrinogen (Human) test is indicated for the detection of thrombus formation in patients undergoing major orthopedic or other surgical procedures, myocardial infarction, pulmonary disease, malignant disease and other medical conditions known to predispose to thromboembolism.

CONTRAINDICATIONS
There are no known contraindications to the use of IBRIN. However, it should be noted that the iodides given to block the uptake of (131I) by the thyroid gland are contraindicated in patients with a known sensitivity to the iodides.

WARNINGS
This radiopharmaceutical should not be administered to patients under 18 years of age, to patients who are pregnant, or to patients who are lactating, unless the information to be gained outweighs the potential risk. Extraordinary precautions have been taken in the preparation of IBRIN (Radionuclide-Labeled (99m) Fibrinogen (Human)) to eliminate the possible transmission of hepatitis. Nevertheless, the remote risk of hepatitis associated with the administration of Radionuclide-Labeled (99m) Fibrinogen (Human) cannot be entirely eliminated. The finding of a positive test within any patient up to six months after the administration of IBRIN should be reported to Amersham for further evaluation, since there are numerous possible sources of hepatitis infection.

PRECAUTIONS
Care should be taken to assure minimum radiation exposure to the patient, consistent with proper patient management, and to assure minimum radiation exposure to occupational workers. This product contains radioactive materials which must be handled only by qualified personnel in conformity with Nuclear Regulatory Commission, agreement state, or other appropriate government regulations. Care must be taken to avoid excessive exposure to its radiation. Shielding or equivalent radiation protective measures must be used. This product is prepared from units of human plasma which have been tested using RIA methods and found non-reactive for Hepatitis B surface antigen. Approved detection methods are not sensitive enough to detect all infectious units of blood or all possible cases of hepatitis. However, IBRIN has been prepared from single donor plasma and has been injected into recipients without evidence of hepatitis B antigen by periodic physical examination and laboratory testing (e.g., tests for hepatitis B antigen and antibody to hepatitis B surface antigen) of the recipients.

ADVERSE REACTIONS
There has been no reported incidence of allergic or anaphylactic reactions following the intravenous administration of IBRIN.
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TechneColl® Sulfur Colloid Kit

for the preparation of Technetium Tc99m Sulfur Colloid

*Based on an estimated average of two patients dosed per vial.

See next page for brief summary.

Mallinckrodt, Inc.
P.O. Box 5840
St. Louis, MO 63134
DESCRIPTION
The kit contains all of the non-radioactive reagents required to prepare 25 ml of Technetium Tc-99m Sulfur Colloid suitable for direct intravenous injection. When sterile, pyrogen-free Sodium Pertechnetate Tc 99m is added to the reaction vial, Technetium Tc-99m Sulfur Colloid is formed with the non-radioactive reagents.

DIRECTIONS
Following intravenous administration, Technetium Tc 99m Sulfur Colloid is rapidly cleared by the reticuloendothelial system from the blood with a nominal clearance half-time of approximately 2.5 minutes. Uptake of the radioactive colloid by organs of the reticuloendothelial system is dependent upon both their relative blood flow rates and the functional capacity of the phagocytic cells. In the average normal patient 80 to 90% of the injected colloid is removed from the plasma within 2 hours. The remainder is trapped by the Kupffer cells of the liver, 5 to 10% by the spleen and the balance by the bone marrow.

INDICATIONS
Technetium Tc 99m Sulfur Colloid is used as an agent for imaging areas of functioning reticuloendothelial cells in the liver, spleen, and bone marrow.

CONTRAINDICATIONS
None.

WARNINGS
The contents of the double-compartment dose syringes are intended only for use in the preparation of Technetium Tc 99m Sulfur Colloid and are not to be directly administered to the patient. 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.

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 who have the necessary experience and training and are authorized to license the use of radionuclides.

Preparations should not be administered to patients who are pregnant or during lactation unless the benefits of the use outweigh the potential hazards.

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

PRECAUTIONS
The components of the kit are sterile and non-pyrogenic. It is essential that the user follow the directions below for strict aseptic procedures during preparation of the colloid.

The stability of the colloidal preparation may be decreased in the presence of polyvalent cations, thus resulting in the agglutination of the individual colloidal particles. Larger particles are likely to be trapped by the pulmonary capillary bed following intravenous injection.

It is recommended that pertechnetate solutions containing more than 10 micrograms/ml of aluminum not be used for formulation of the Technetium Tc-99m Sulfur Colloid.

Technetium Tc 99m Sulfur Colloid 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 agglutination with aging, a batch of Technetium Tc 99m Sulfur Colloid not be used after six hours from the time of formulation.

As in the use of any other radioactive material care should be taken to ensure minimal radiation exposure to the patient, auxiliary personnel, and to insure minimum radiation exposure to occupational workers.

ADVERSE REACTIONS
Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving sulfur colloid preparation. Although rare, pyrogen reactions have been reported following the administration of the drug stabilized with gelatin. Arm pain following injection has been reported.

DIRECTIONS FOR PREPARATION
Note: Read complete directions thoroughly before starting preparation procedure.

PROCEDURAL PRECAUTIONS
1. All transfer and vial stopper entries must be done using aseptic technique.
2. The Technecol Kit should be stored at room temperature (approximately 25°C).
3. All Technecol Kit reagents must be at room temperature before use. At lower temperatures, there may be evidence of undissolved gelatin in the double-compartment syringes. The syringes should be allowed to stand at room temperature (approximately 25°C) until the gelatin returns to solution. Do not warm the syringes by placing in an incubator.
4. The water bath used for heating the contents of the Reaction Vial must be at a continuous rolling boil during the two heating steps of the preparation procedure. The Reaction Vial should be in direct contact with the boiling water bath and the level of the bath must be at least even with the level of the contents of the Reaction Vial.
5. If the Reaction Vial is incubated in a lead safe, the temperature of the safe should be allowed to reach the temperature of the water bath before incubating the Reaction Vial.
6. As a result of heating the contents of the closed Reaction Vial, internal pressure will be created causing some resistance when injecting the contents of Syringe II into the Reaction Vial. The resistance may be minimized either by employing a syringe to evacuate approximately 30 ml of air from the Reaction Vial before the addition of the generator eluate (Step 3) or by venting the Reaction Vial with a sterile needle prior to injecting the contents of Syringe II into the Reaction Vial (Step 7). If venting is used, remove vent needle before returning Reaction Vial to water bath.
7. When attaching the disposable needles to the double-compartment syringes, care must be taken to insure that the needles are firmly attached to the syringes.

PROCEDURE: for preparing Technetium Tc 99m Sulfur Colloid
Note: The radioactive material should be shielded at all times during preparation.
1. Prepare a rolling boil water bath.
2. Fill in the necessary information on the “Caution: Radioactive Material” label and place directly over the yellow area provided on the Reaction Vial label. Insert the string tag to the neck of the Reaction Vial. Place the Reaction Vial in a lead Dispensing Shield fitted with a lid and with a minimum wall thickness of 3/8 inch.
3. After swabbing the rubber stopper of the Reaction Vial with an appropriate antiseptic, aseptically inject a calculated volume of technetium-99m generator eluate or prepacaged sodium pertechnetate Tc 99m into the Reaction Vial. The volume of pertechnetate solution used must be between 0.1 and 3.0 ml. (Withdraw a 5 ml or greater volume of air to relieve pressure.)
4. Aseptically assemble Syringe I and aseptically inject the contents into the Reaction Vial.
5. Invert the Reaction Vial several times to obtain complete mixing.
6. Immediately transfer the Reaction Vial to a lead (minimum wall thickness of 1/8 inch) boiling vessel which has been heated to the temperature of the rolling boil water bath. This may be accomplished by placing the shield in the boiling roll bath a few minutes prior to transferring the Reaction Vial. The level of the water bath must be even with or above the contents of the Reaction Vial. Allow the Reaction Vial to incubate for 8 minutes.
7. Aseptically assemble Syringe II immediately after the incubation period (Step 6) remove the Reaction Vial from the Boiling Shield and place in the Dispensing Shield. Swab the vial stopper with an appropriate antiseptic and aseptically inject the contents of the Syringe II into the Reaction Vial.
8. Immediately return the Reaction Vial to the Boiling Shield and incubate for 2 minutes.
9. Remove the Reaction Vial from the Boiling Shield and place in the Dispensing Shield. Allow the contents of the Reaction Vial to cool for approximately 15 minutes to reach body temperature. The final Technetium Tc 99m Sulfur Colloid preparation should be clear to slightly hazy in appearance, but there should be no flocculent present. If a precipitate is visible, the preparation should not be used.
10. Calibrate the radioactivity concentration of the Technetium Tc 99m Sulfur Colloid and fill in the appropriate information on the string tag. Do not use this material after 6 hours from time of preparation.

Calculation of Radioactivity Concentration
ml/Ci of colloid = ml of Tc99m added ml of Tc99m added + 5 mils
**The total delivered non-radioactive reagent volume employed in the preparation is 5 ml

DOSAGE AND ADMINISTRATION
The suggested intravenous dose range used in the average patient (70 kg) is 1 to 8 milliliters of Technetium Tc 99m Sulfur Colloid.

When orally administered, the Technetium Tc 99m Sulfur Colloid is not absorbed from the GI tract. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

HOW SUPPLIED
Catalog Number Technecol Kit 090 Package contains - 5 Preparation Units for the preparation of Technetium Tc 99m Sulfur Colloid.

Each Preparation Unit Contains:
1. Reaction Vial: Contents 2.0 ml each ml contains 50 mg phosphoric acid.
2. Syringe I (2-compartment disposable syringe) — Component A, 1.1 ml. Each ml contains 12 mg gelatin and 9 mg sodium chloride. Component B, 0.55 ml. Each ml contains 12 mg sodium thiosulfate.
3. Syringe II (2-compartment disposable syringe) — Component A, 0.6 ml. Each ml contains 36 mg gelatin and 9 mg sodium chloride. Component B, 1.0 ml. Each ml contains 544 mg sodium edetate and 4 mg disodium edetate.
4. Disposable needles.
6. Radioactivity information string tag.
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New Agent for Liver Scintigraphy

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Aggregated Albumin (Human) Kit

**DESCRIPTION**
- The kit contains 6 sterile vials containing 5-11 mg of pre-gelatine aggregated albumin (human), 0.67 - 0.83 mg, at 18 mg, sodium chloride. When dried, potassium the sodium pentasaccharide Te-99m is added to the kit. Technetium labeled macroaggregated human serum albumin (Technetium MA, 99m Technetium Macroparticles) is formed. The particles disperse into the lungs in the pulmonary vasculature in the presence of the serum albumin. The formation of normal serum albumin (HSA) through and/or adjustment. Sodium hydroxide of the hydroxy product may be present in variable amounts. At least 99% of the macroaggregated particles are less than 380 nm in size. The granul lethal dose of 10 to 70 hours. None larger than 0.15 mg. Vials contain 10 units of 0.8 - 0.2 million particles per mg. The labeling efficiency is essentially quantitative and the bound Tc-MAA remains stable in vivo throughout the indicated period after administration.

**APPLICATIONS**
- Application has been found with the U. S. Nuclear Regulatory Commission for distribution of this kit to persons licensed pursuant to 331 and 335 100, Group B of ORF Part 30, or under equivalent licenses of agreement states, and is still pending.

**ACTIONS**
- Following intravenous injection, Technetium MA, 99m is rapidly transmitted to the blood stream to the lungs. The aggregates do not enter the tissues of the lungs, but remain in the pulmonary vasculature. When pulmonary blood flow is normal, the material is carried throughout the entire lung field, when pulmonary blood flow is diminished or obstructed by a disease process, the particles are correspondingly prevented in part or in whole from passage through the affected portion of the pulmonary vasculature. Technetium Macroparticles remain in the lungs for variable amounts of time depending on particle size. The particles decrease from the lungs in the lungs in an order of pharmaceutical with the larger aggregate aggregates having the longer half-life. The half-life of the particles ranging from 10 - 90 minutes in diameter usually have a half-life of 2-8 hours. Apparently, the aggregates are not detected by the pulmonary capillaries where the particles are broken down until they are small enough to pass. In rats 4-5% of the 99m-Tc remains in the lungs after 24 hours.

**INDICATIONS**
- Scintillation scanning of the lungs with Technetium Macroparticles is indicated as an adjunct to other diagnostic procedures whenever information about pulmonary vasculature is desired. These techniques require clinical applications of lung scanning have been outlined by one investigator. 1) The diagnosis of pulmonary embolism. 2) Identification of local conditions such as hyper or hyper capillary pulmonary emboli. 3) Determination of the degree of pulmonary circulation in pulmonary and or, evaluation of the patient's ability to withstand pulmonary surgery.

**CONTRAINDICATIONS**
- The presence of right to left shunts which would allow Technetium MA, 99m to be a systemic agent in contamnation to be used in the material. Particular material such as Technetium MA, 99m should not be administered to patients in evidence of severe restriction to pulmonary blood flow such as may be present in pulmonary hypertension.

**WARNINGS**
- Technetium MA, 99m should not be administered to patients who are pregnant, or during laboration unless the benefits are to be gained outweigh the potential hazards.

**PRECAUTIONS**
- As in the use of any other radioactive material care should be taken to ensure minimum exposure to the patient, consistent with patient performance, and to ensure minimum radiation exposure to staff and occupational workers.

**REFERENCES**

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of equipment
INDICATIONS AND USAGE: Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin may be used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINDICATIONS: None known.

WARNINGS: Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin should not be administered to patients who are pregnant or lactating 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 menstruation.

It has been reported that false-positive or false-negative brain scans may result when brain scans using sodium pertechnetate Tc 99m are performed after a bone scan has been done using an agent containing stannous chloride, e.g., a pyrophosphate or polyphosphate bone agent. This is thought to be due to the interaction of Tc 99m with stannous ions inside red blood cells.

Therefore, in those cases where both brain and bone scans are indicated, the brain scan should be performed first, if feasible. Alternatively, another brain imaging agent, such as Tc 99m DTPA, may be employed.

PRECAUTIONS: Tc 99m Pyrophosphate/Trimetaphosphate-Tin, 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 clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often thereafter as possible for the next 4-6 hours.

Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin should be used within six hours of preparation.

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 adverse effects on the fetus. Tc 99m Pyrophosphate/Trimetaphosphate-Tin 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: No adverse reactions specifically attributable to the use of Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin have been reported.

DOSE AND ADMINISTRATION: The suggested dose range for i.v. administration to be employed in the average patient (70kg) is:

- Bone Imaging: 5-15mCi Tc 99m labeled Pyrophosphate/Trimetaphosphate-Tin.
- Scanning post-injection is optimal at about 3-4 hours.

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

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.

The components of the New England Nuclear Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin Kit are supplied sterile and non-pyrogenic. Asperic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during addition of pertechnetate solution and the withdrawal of doses for patient administration.

Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin is prepared by simply adding 3-7mCi of sodium pertechnetate Tc 99m solution to the vial and swirling for about one minute. Shielding should be utilized when preparing the Tc 99m Pyrophosphate/Trimetaphosphate-Tin.

HOW SUPPLIED: NEN'S PYROLITE™ Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin Kit is supplied as a set of five or thirty vials, sterile and non-pyrogenic. Each vial contains in lyophilized form:

- Sodium Pyrophosphate - 10mg
- Sodium Trimetaphosphate - 30mg
- Stannous Chloride - 1mg

Prior to lyophilization the pH is adjusted to between 4.5-5.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial are lyophilized and stored under nitrogen. Store at room temperature (15-30°C).

Included in each five (5) vial kit is one (1) package insert and twelve (12) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and seventy-two (72) radiation labels.
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<table>
<thead>
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<th>FEATURE</th>
<th>CRC-5</th>
<th>CRC-5R</th>
<th>CRC-5M</th>
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For brief summary of prescribing information, please see next page.
WARNINGS

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.

TechneScan PYP Tc 99m should not be used more than six hours after preparation.

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.

Bone Imaging
Both prior to and following TechneScan PYP Tc 99m administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the TechneScan PYP Tc 99m 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.

DOSAGE AND ADMINISTRATION

The recommended adult dose of TechneScan PYP is:

1. Skeletal Imaging — 5 to 15 millicuries (1 to 14 milligrams stannous pyrophosphate).
2. Cardiac Imaging — 10 to 15 millicuries (4 to 7 milligrams stannous pyrophosphate).

TechneScan PYP Tc 99m is injected intravenously over a 10- to 20-second period. For optimal results, bone imaging should be done 1 to 6 hours following administration. Cardiac imaging should be done 60 to 90 minutes following administration. The acute myocardial infarction can be visualized from 24 hours to 9 days following onset of symptoms, with maximum localization at 48 to 72 hours. Cardiac imaging should be done with a gamma scintillation camera. It is recommended that images be made of the anterior, left anterior oblique and left lateral projections.

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

HOW SUPPLIED

Catalog Number—094 TechneScan PYP Kit

Kit Contains:

5—Stannous Pyrophosphate Reaction Vials (Lyophilized) for the preparation of Technetium Tc 99m Stannous Pyrophosphate.

Reaction Vial Contains:

15.4 mg Sterile Stannous Pyrophosphate (Lyophilized). Hydrochloric acid is added for pH adjustment prior to lyophilization.

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<th>Syringe Shield</th>
<th>Model</th>
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</table>

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With every Syringe Shield order over $190.00, a $^{99m}$Tc DECAY CLOCK (which simplifies the calculation of individual patient doses) will be included WITHOUT CHARGE . . . while the supply lasts. Get yours now!

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