Technetium Tc 99m Generator

Secondary shield to further reduce radiation

5cc and 10cc elution vials

Elution vial shields

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TECHNETIUM 99m GENERATOR for the Production of Sodium Pertechnetate Tc 99m

DESCRIPTION: The Technetium Tc 99m Generator is prepared with fissile produced Molybdenum Mo 99 absorbed on alumina in a lead-shielded column and provides a means for obtaining sterile pyrogen-free solutions of Sodium Pertechnetate Tc 99m in sodium chloride injection. The solution should be crystal clear. With a p.d. of 4.5-5.5, hydronium acid and/or sodium hydroxide may be used for pH adjustment. Over the life of the generator, an elution will contain a yield of 60% to 100% of the theoretical amount of Technetium Tc 99m available from the Molybdenum Mo 99 on the generator column.

Each eluate of the generator should not contain more than 0.15 microcuries of the Molybdenum Mo 99 per millicurie Technetium Tc 99m per administered dose. The time of administration, and not more than 10 micrograms of aluminum per milliliter of the generator eluate, both of which must be determined by the user before administration.

INDICATIONS AND USAGE: Sodium Pertechnetate Tc 99m is used in ADULTS as an agent for brain imaging including central radionuclide angiography; thyroid imaging; salivary gland imaging; placenta localization; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotope cystography) for detection of vesico-urethral reflux. Sodium Pertechnetate Tc 99m is used in CHILDREN as an agent for brain imaging including central radionuclide angiography; thyroid imaging; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotope cystography) for detection of vesico-urethral reflux.

CONTRAINDICATIONS: None known.

WARNINGs: Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults. In general, the younger the child the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

PRECAUTIONS: 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 ensure minimum radiation exposure to occupational workers.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m may affect fertility in males or females.

Pregnancy Category C
Animal reproductive studies have not been conducted with Technetium Tc 99m. It is also not known whether Technetium Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be given to a pregnant woman only if the expected benefits to be gained clearly outweigh the potential hazards.

ADVERSE REACTIONS: Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

NOW SUPPLIED: Sodium Pertechnetate Tc 99m is supplied as a Molybdenum Mo 99/Technetium Tc 99m generator in sizes from 830 millicuries to 16,600 millicuries (in approximately 830 millicuries increments) of Molybdenum Mo 99 as of 10:00 P.M. Eastern Time of the day of calibration. The TECHNETIUM 99m GENERATOR consists of:
1) sterile generator,
2) Sodium Chloride Injection source,
3) 10 cc sterile evacuated vials,
4) sterile needles,
5) elution vial shield,
6) evacuated drug tablets.

Stable elution vials in 5 cc and 25 cc sizes are available upon request.

"initial order only"

The TECHNETIUM 99m GENERATOR should not be used after sixteen (16) days from the date and time of calibration.

 Jointly manufactured by:
 CINTICHEM, INC.
 Tuxedo, N.Y. 10987
 and
 UNION CARBIDE CORPORATION
 Tuxedo, N.Y. 10987

June, 1983

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Raytheon Medical Systems has harnessed the imaging power of our exclusive, fourth generation 91-tube detector – complete with variable linearity circuitry – to the profession’s most precise gantry system, table and image processing to create the Spectrum 91. The result is the first optimized ECT system... with uncompromised planar capability.

State of the art.
The Spectrum 91 ECT System uses advanced robotics technology for total motion control. Four independent CPU units are the heart of the system. Simultaneously, they control gantry rotation, detector angle and parallelism.

True body contour acquisition covers a full 360°... plus circular and elliptical orbiting. All motions are electronically encoded for ±0.1° control... and to make sure the axis of rotation remains unchanged during body contouring. “Teaching” the gantry is fast... easy... effortless. It can retrace virtually any contour after only two minutes of patient-specific programming. What’s more, automatic parallelism of the detector head minimizes complex setup routines common to SPECT protocols.

Total imaging performance.
Spectrum 91 ECT gives you positive imaging control – two ways. First, the Raytheon Digital Parameter Controller gives you fast, accurate and repeatable entry and monitoring functions of all study, system and patient parameters. Status verification is positive... and reassuring.

But that’s not all. The Spectrum 91 ECT System can also interface with a variety of computer systems for both gantry control and imaging capability. So the operational choice is left up to you.

Couple all this capability with a unique, interlocking carbon fiber table that easily simplifies all patient imaging... and you’ll see exactly why the Spectrum 91 ECT System is a first in so many ways.

Find out about Raytheon’s exclusive Spectrum 91 ECT System with a call to your Raytheon dealer. Or contact Raytheon Medical Systems, 2020 North Janice Avenue, Melrose Park, IL 60160. Phone 1-800-323-2213. In Illinois, 1-312-865-2600.

Raytheon Medical Systems has harnessed the imaging power of our exclusive, fourth generation 91-tube detector – complete with variable linearity circuitry – to the profession’s most precise gantry system, table and image processing to create the Spectrum 91. The result is the first optimized ECT system... with uncompromised planar capability.

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More than 80% lung uptake for reliable biological efficacy

Low supernatant activity (SA) and very high radiochemical purity (RCP) help assure biological efficacy you can depend on time after time.

The only MAA product indicated for use in isotopic venography

Please see adjacent page for brief summary.
DESCRIPTION
Macrotec is a sterile, non-pyrogenic, lyophilized preparation of Albumin Aggregated. Each 5 mL vial of Macrotec contains 15 mg of Albumin Aggregated, 10.0 mg Albumin Human, 0.06 mg (minimum) stannous chloride (maximum stannous and stannic chloride 0.16 mg), 1.8 mg of sodium chloride with trace amounts of sodium acetate, acetic acid and hydrochloric acid. Macrotec contains no preservatives. The pH of the reconstituted product is between 3.8 and 8.0.

The aggregated particles are formed by denaturation of Albumin Human in a heating and precipitation process. Each vial contains 1-8 million particles, 90% of which are between 10 and 90 microns in size. The average size is 20 to 40 microns; no particles are greater than 150 microns.

Reconstitution of Macrotec with sterile sodium pertechnetate Tc-99m forms an aqueous suspension of Technetium Tc 99m Albumin Aggregated for diagnostic use by intravenous injection. No less than 90% of the pertechnetate Tc-99m added to the reaction vial is bound to the aggregates at preparation time and remains bound throughout the 6-hour lifetime of the suspension.

INDICATIONS AND USAGE
Lung Imaging
Macrotec (Technetium Tc 99m Albumin Aggregated Injection) is a lung imaging agent which may be used as an adjunct in the evaluation of pulmonary perfusion in adults and children. It is useful in the early detection of pulmonary emboli and in the evaluation of the status of the pulmonary circulation in such conditions as pulmonary neoplasm, pulmonary tuberculosis and emphysema.

Isotopic Venography
Macrotec is also indicated for use in isotopic venography as an adjunct in the screening, diagnosis and management of deep vein thrombosis in the lower extremities. Combined isotopic venography of the lower extremities and the pulmonary vasculature may be performed.

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

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

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

PRECAUTIONS
General
In patients with right to left heart shunts, additional risk may exist due to the rapid entry of Albumin Aggregated into the systemic circulation. The safety of this agent in such patients has not been established.

Hypersensitivity reactions are possible whenever protein-containing materials such as pertechnetate labeled Albumin Aggregated are used in man. Epinephrine, antihistamines and corticosteroids should be kept available for immediate use.

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

The components of the Macrotec (Technetium Tc 99m Albumin Aggregated Kit) are sterile and non-pyrogenic. It is essential to follow directions carefully and adhere to strict aseptic procedures during preparation.

Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Albumin Aggregated Injection and are NOT to be administered directly to the patient.

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

The technetium Tc-99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, sodium pertechnetate Tc-99m containing oxidants should not be employed.

The preparation contains no bacteriostatic preservative. Technetium Tc 99m Albumin Aggregated Injection should be stored at 2-8°C and discarded 6 hours after formulation.

Technetium Tc 99m Albumin Aggregated Injection is a physically unstable suspension and consequently the particles settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactive particles.

If blood is drawn in the syringes, unnecessary delay prior to injection may result in clot formation.

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.

As in the use of any other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to clinical personnel.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Albumin Aggregated Injection affects fertility in males or females.

Pregnancy Category C
Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc-99m Albumin Aggregated Injection. It is also not known whether Technetium Tc 99m Albumin Aggregated Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc 99m Albumin Aggregated Injection should be given to a pregnant woman only if clearly needed.

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.

Nursing Mothers
Technetium Tc-99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use
The lowest possible number of particles should be used in the right-to-left shunting, in neonates and in severe pulmonary disease.

ADVERSE REACTIONS
Although adverse reactions specifically attributable to the Technetium Tc-99m Albumin Aggregated Injection have not been noted, the literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc-99m Albumin Aggregated have been reported.

HOW SUPPLIED
Macrotec (Technetium Tc-99m Albumin Aggregated) is supplied as a kit containing 10 reaction vials (5 mL size).
This tiny package contains all it takes to make an oak tree
Introducing

Starcam

The revolution in nuclear imaging
Using advanced digital technology, General Electric has engineered a totally compact, integrated nuclear diagnostic system that gives you exceptional imaging capability and enhanced departmental productivity... in a single system. With the Starcam system, all acquisition functions are computer controlled. That means peak camera performance is maintained at all times, providing consistently high quality images. Our large image monitor offers acquisition and display in matrices up to 512², making images easier to view and giving you the best possible resolution.

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Starcam is available in 300, 400 and 500 mm configurations. And General Electric's field proven Autotune detectors, integral to the Starcam system, automatically adjust photo multiplier tubes "on-the-fly," stabilizing camera performance and reducing system downtime and maintenance caused by PM tube drifting. Digital "on-the-fly" energy and spatial corrections provide improved linearity, uniformity and overall image resolution.

Starcam features dual central processing units with over one megabyte of very high-speed expandable memory that's directly accessible for display and processing. An 84-megabyte Winchester disc, standard with Starcam, gives you more than twice the data storage available with other systems.

The bottom line...productivity
Starcam is a breakthrough in imaging technology. It provides today's nuclear departments with procedural capabilities unsurpassed by any other system. It redefines the operation of your department, eliminating many time-consuming functions without compromising the diagnostic value of the information obtained. The result is a more effective, efficient imaging department: one that optimizes diagnostic capability without jeopardizing the economic well-being of your health care institution.

Starcam represents General Electric's continued commitment to developing nuclear diagnostic imaging technology that's innovative today and designed to stay that way tomorrow.

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images with the roomlight too!

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Now, watch the monitor on your multiformat camera as your Kodak representative helps you arrive at the specific look you like. Then, drawing on special training and experience, and the Kodak video display analyzer, your technical sales representative can—with many multiformat cameras—literally "put numbers” on that look.

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MICROLITE™
Technetium Tc 99m Albumin Colloid Kit

The first "no boil" instant colloid kit for consistent liver/spleen and bone marrow imaging

Provides convenience, safety and quality images diagnostically equivalent to sulfur colloid

- **SAVES TIME**
  - one-step preparation, no need to boil, ready to inject

- **CONSISTENT QUALITY**
  - less chance of product variations during preparation

- **REDUCES PREPARATION ERROR**
  - simple procedure, just add technetium 99m and swirl

- **MINIMIZES EXPOSURE**
  - less handling, shorter prep times, helps meet ALARA guidelines

MICROLITE™
Kit for use in the preparation of Technetium Tc 99m Albumin Colloid

INDICATIONS AND USAGE: Technetium Tc 99m Albumin Colloid is indicated for use as a diagnostic imaging agent for visualization of the functioning reticuloendothelial (RES) system of the liver, spleen, and bone marrow.

CONTRAINDICATIONS: Technetium Tc 99m Albumin Colloid is contraindicated for persons with a history of hypersensitivity to products containing human serum albumin.

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

PRECAUTIONS: 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 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 not 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 carefully and adhere to strict aseptic procedures during preparation of the radiopharmaceutical.

Technetium Tc 99m Albumin Colloid should be used within 6 hours of 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 clot formation in it.

Do not use if clumping of the contents is observed.

Technetium Tc 99m Albumin Colloid (MICROLITE) as well as other radioactive drugs should be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patient consistent with proper patient management.

Carcinogenesis, Mutagenesis, Impairment of fertility:
No animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Albumin Colloid affects fertility in males or females.

Pregnancy Category C:
Animal reproductive studies have not been conducted with Technetium Tc 99m Albumin Colloid. It is also not known whether Technetium Tc 99m Albumin Colloid can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc 99m should be given to a pregnant woman only if clearly needed.

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 mens

Nursing Mothers:
Technetium Tc 99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feeding.

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

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

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

ADVERSE REACTIONS:
Although no adverse reactions associated with the use of Microlite have been reported, hypersensitivity reactions are theoretically possible as protein-containing materials such as Tc 99m-labeled aggregated albumin are used in man. Epinephrine, antihistamines, and corticosteroids should be available for use in the event such a reaction occurs.

DOSEAGE AND ADMINISTRATION:
The recommended intravenous dose range for the average (70 kg) patient is 37-290 MBq (1-8 mCi).

The patient dose should be measured by a suitable radiotracer calibration system immediately prior to patient administration. Re-suspend colloid by repeated inversion of the shielded vial immediately prior to withdrawal of dose into syringe. Inject the vial for foreign particulates. Do not administer if foreign particulates are found in the colloid. If blood is drawn into the syringe, any unnecessary delay prior to injection may lead to clot formation in it. Do not backflush the syringe. Slow injection is recommended and for optimum results imaging may begin about 15 minutes after injection. Radiographic quality images are usually obtained 20 minutes after intravenous injection. The patient should be observed for at least 15 minutes after injection. For ophtalmic, urographic, and other body function imaging, the patient should be observed in the imaging area for at least 15 minutes after injection.

How Supplied:
MICROLITE™ Kit for use in the preparation of Technetium Tc 99m Albumin Colloid is supplied in kits of five or thirty vials, sterile and non-pyrogenic, each vial containing:

<table>
<thead>
<tr>
<th>Component</th>
<th>Content</th>
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<tbody>
<tr>
<td>Albumin Colloid</td>
<td>1 mg</td>
</tr>
<tr>
<td>Normal Human Serum Albumin</td>
<td>10 mg</td>
</tr>
<tr>
<td>Total Tc, maximum (as stannous chloride SCl2) 2H2O</td>
<td>0.17 mg</td>
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<tr>
<td>Stannous Chloride (S2Cl2)</td>
<td>0.07 mg</td>
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<tr>
<td>Poloxamer 188</td>
<td>1 mg</td>
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<tr>
<td>Diethanolamide</td>
<td>0.13 mg</td>
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<tr>
<td>Sodium Phosphate (anhydrous)</td>
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Prior to lyophilization the pH is adjusted with HCl and/or NaOH. The contents of the vial are lyophilized and stored under nitrogen. Included in each five (5) vial kit are one (1) package insert and twelve (12) radiation labels. Included in each thirty vial kit is one (1) package insert and seventy-two (72) radiation labels. Before reconstitution store at room temperature (15°-30°C) and protect from light.

The components of the kit for use in the preparation of Technetium Tc 99m Albumin Colloid are supplied sterile and non-pyrogenic. Aseptic 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 Albumin Colloid is prepared by adding 2.8 ml of pertechnetate solution to the vial and swirling for about one minute. Shielding should be utilized when preparing the Technetium Tc 99m Albumin Colloid.

Catalog Number NRP-470 (5-Vial Kit)
Catalog Number NRP-470C (30-Vial Kit)
May 1984 51166

SUPPLEMENTS

3 Includes the original pamphlet #5: "Estimates of absorbed fractions for monoenergetic photon sources uniformly distributed in various organs of a heterogeneous phantom." (1969)

6 Includes pamphlet #9: "Radiation dose to humans from 32P Selenomethionine." (1972)

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<thead>
<tr>
<th>Pamphlets</th>
<th>Supplements</th>
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<tbody>
<tr>
<td>1</td>
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To provide up-to-date information about the most accurate procedures for ensuring quality control of radiopharmaceuticals, The Society of Nuclear Medicine presents *Chromatography of Technetium-99m Radiopharmaceuticals—A Practical Guide*.

This new manual offers readers a collection of miniaturized chromatographic methods for the rapid and precise determination of the radiochemical purity of commonly used Tc-99m radiopharmaceuticals.

Topics covered include the nature and source of impurities, principles and classic techniques of chromatography, methods for counting miniature chromatographic strips, and pitfalls of miniature methods and how to avoid them. Also contained herein is a listing of each radiopharmaceutical with the USP criteria for radiochemical purity, typical scans of impure products, and standards and interlaboratory comparisons for miniaturized systems.

Prepared to aid nuclear medicine personnel in implementing voluntary quality-assurance programs, the material may also be used as a training resource for individuals preparing for professional licensure and certification.

**Ordering Information:**
Add $2.50 postage and handling for each book ordered. Prepayment required in U.S. funds drawn on U.S. banks only. For payments made in U.S. dollars, but drawn on a foreign bank, add a bank processing fee of $4.50 for Canadian bank drafts or $40.00 for all other foreign bank drafts. Check or purchase order must accompany all orders. Make checks payable to: The Society of Nuclear Medicine. *Prices are in U.S. dollars and are subject to change without notice.*

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SQUIBB™ Diagnostics
DESCRIPTION
Macrotec is a sterile, non-pyrogenic, hyophilized preparation of albumin aggregated. Each 5 mL vial of Macrotec contains 15 mg of Albumin Aggregated, 10.0 mg Albumin Human, 0.06 mg (minimum) stannous chloride (maximum stannous and stannic chloride 0.16 mg), 1.6 mg of sodium chloride with trace amounts of sodium acetate, acetic acid and hydrochloric acid. Macrotec contains no antioxidants. The pH of the reconstituted product is between 3.8 and 8.0.

The aggregated particles are formed by denaturation of Albumin Human in a heating and precipitation process. Each vial contains 1-6 million particles, 90% of which are between 10 and 90 microns in size. The average size is 20 to 40 microns; no particles are greater than 150 microns.

Reconstitution of Macrotec with sterile sodium pertechnetate Tc-99m forms an aqueous suspension of Technetium Tc 99m Albumin Aggregated for diagnostic use by intravenous injection. No less than 95% of the pertechnetate Tc-99m added to the reagent vial is bound to the aggregates at preparation time and remains bound throughout the 6-hour lifetime of the suspension.

INDICATIONS AND USAGE
Lung Imaging
Macrotec (Technetium Tc 99m Albumin Aggregated Injection) is a lung imaging agent which may be used as an adjunct in the evaluation of pulmonary perfusion in adults and children. It is useful in the early detection of pulmonary emboli and in the evaluation of the status of the pulmonary circulation in such conditions as pulmonary neoplasm, pulmonary tuberculosis and emphysema.

Isotopic Venography
Macrotec is also indicated for use in isotopic venography as an adjunct in the screening, diagnosis and management of deep vein thrombosis in the lower extremities.

Combined isotopic venography of the lower extremities and the pulmonary vasculature may be performed.

CONTRAINDICATIONS

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

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

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

PRECAUTIONS

General
In patients with right to left heart shunts, additional risk may exist due to the rapid entry of Albumin Aggregated into the systemic circulation. The safety of this agent in such patients has not been established.

Hypersensitivity reactions are possible whenever protein-containing materials such as pertechnetate labeled Albumin Aggregated are used in man. Epinephrine, antihistamines and corticosteroids should be kept available for immediate use.

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

The components of the Macrotec (Technetium Tc 99m Albumin Aggregated Kit) are sterile and non-pyrogenic. It is essential to follow directions carefully and adhere to strict aseptic procedures during preparation.

Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Albumin Aggregated Injection and are NOT to be administered directly to the patient. The contents of the kit before preparation are not radioactive. However, after the sodium pertechnetate Tc-99m is added, adequate shielding of the final preparation must be maintained.

The technetium Tc-99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, sodium pertechnetate Tc-99m containing oxidants should not be employed.

The preparation contains no bacteriostatic preservative. Technetium Tc-99m Albumin Aggregated Injection should be stored at 2-8°C and discarded 6 hours after reconstitution.

Technetium Tc-99m Albumin Aggregated Injection is a physically unstable suspension and consequently the particles settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactive particles.

If blood is drawn into the syringes, unnecessary delay prior to injection may result in clot formation.

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.

As in the use of any other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to clinical personnel.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc-99m Albumin Aggregated Injection affects fertility in males or females.

Pregnancy Category C
Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc-99m Albumin Aggregated Injection. It is also not known whether Technetium Tc-99m Albumin Aggregated Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc-99m Albumin Aggregated Injection should be given to a pregnant woman only if clearly needed.

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 menstus.

Nursing Mothers
Technetium Tc-99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use
The lowest possible number of particles should be used in the right-to-left shunting, in neonates and in severe pulmonary disease.

ADVERSE REACTIONS
Although adverse reactions specifically attributable to the Technetium Tc-99m Albumin Aggregated Injection have not been noted, the literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc-99m Albumin Aggregated have been reported.

HOW SUPPLIED
Macrotec (Technetium Tc 99m Albumin Aggregated) is supplied as a kit containing 10 reaction vials (5 mL size).


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SQUIBB Diagnostics
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1. (Revised) A revised schema for calculating the absorbed dose from biologically distributed radionuclides (1976)
2. (Revised) Estimates of specific absorbed fractions for photon sources uniformly distributed in various organs of a heterogeneous phantom (1978)
3. Radionuclide decay schemes and nuclear parameters for use in radiation-dose estimation (1975)
4. ‘S’ absorbed dose-per-unit cumulated activity for selected radionuclides and organs (1975)

**SUPPLEMENTS**

3. Includes the original pamphlet #5: "Estimates of absorbed fractions for monoenergetic photon sources uniformly distributed in various organs of a heterogeneous phantom." (1969)

6. Includes pamphlet #9: "Radiation dose to humans from 99m-Tc-Selenomethionine." (1972)

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