TECHNETIUM 99m
GENERATORS
Technetium Tc 99m Generators
for the Production of
Sodium Pertechnetate Tc 99m

20 Sizes
Sodium Pertechnetate Tc 99m is used in adults as an agent for:

**INDICATIONS AND USAGE:**

- From the time of generator elution.
- Angiography; and urinary bladder imaging (direct isotopic cystography) for the detection of vesicoureteral reflux.

Sodium Pertechnetate Tc 99m is used in children as an agent for:

- Brain imaging including radionuclide angiography; placenta localization; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for detection of vesicoureteral reflux.

**CONTRAINDICATIONS:**

None known.

**Sodium Pertechnetate Tc 99m**

**HOW SUPPLIED:**

The Technetium Tc 99m Generator is prepared with fission produced Molybdenum Mo 99 absorbed on alumina in lead-shielded columns and provides a means for obtaining sterile pyrogen-free solutions of Sodium Pertechnetate Tc 99m in sodium chloride injection. The eluate should be crystal clear. With a pH of 5.5-7.5, hydrochloric acid and/or sodium hydroxide may have been used for pH adjustment. Over the life of the generator, an elution will contain a yield of 80% 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 0.16 microcurie of the Molybdenum Mo 99 on the generator column.

Each eluate of the generator should not contain more than 15 microcurie of the Molybdenum Mo 99 per milliliter of Tc 99m per administering dose at the time of administration, and not more than 1 microcurie 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 cerebral radionuclide angiography; thyroid imaging; salivary gland imaging, patients localization; blood pool imaging including radionuclide angiography, and urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux.

**Sodium Pertechnetate Tc 99m** is used in children as an agent for:

- Brain imaging including cerebral radionuclide angiography; thyroid imaging; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for the detection of vesico-ureteral 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 absorption of radiation doses and longer life expectancy. These greater risks should be taken 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 insure minimum radiation exposure to occupational workers. Since the eluate does not contain an antimicrobial agent, it should not be used after twelve hours from the time of generator elution or 6 hours after reconstitution of the kit, whichever is earlier.

The small sizes 5, 10 and 20cc vials allow you maximum flexibility in elution concentration to meet your needs.

**Maximum Radiation Protection**

The smallest 5 sizes of the Technetium Tc 99m Generator—830, 1660, 2480, 3310 and 4140 mCi—are shielded with lead. The remaining fifteen sizes are shielded with depleted uranium internal shielding. Depleted uranium possesses greater density and therefore offers superior shielding properties for our higher activity Generators. Optimum shielding design minimizes radiation to personnel in work areas, providing maximum protection.

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**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.

Radiopharmaceuticals, especially those effective in nature, of a technical risk under WARNINGS.

**Nursing Mothers**

Technetium Tc 99m is excreted in human milk during lactation, and therefore formula feedings should be substituted for breast feedings.

**Pediatric Use**

See INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION. See also description of additional risk under WARNINGS.

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

The generator should not be used after 16 days from the date and time of calibration. At time of administration, the solution should be crystal clear.

**ADVERSE REACTIONS:**

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

Technetium Tc 99m generator in sizes from 830 millicuries up to 16,600 milllicuries (in approximately 830 millicurie Increments) of Molybdenum Mo 99 at 10:00 p.m. Eastern Time of the day of calibration. The TECHNETIUM Tc 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. finished drug labels.

Elution vials in 5 cc and 20 cc sizes are available upon request.

Technetium Tc 99m may affect fertility in males or females.

**CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY**

Long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m may affect fertility in males or females.

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Myoscint may enhance diagnosis, assessment of myocardial infarction

Imaging techniques currently used to evaluate myocardial infarction (MI) have a major drawback: They do not permit differentiation between myocardial necrosis and ischemia in the early hours following infarction. Thallium-201, for example, concentrates only in normal myocardial cells. The bone scanning agent technetium-99m pyrophosphate is taken up by necrotic, as well as by some reversibly damaged cells, and also by overlapping ribs. These agents are of limited use for differentiating between irreversible necrosis and severe ischemia. Yet the ability to make that distinction—and make it quickly—could significantly improve management of cardiac patients.

Myoscint™, an imaging agent based on a monoclonal antibody specific to cardiac myosin, may fill this void in cardiac imaging technology. Because this MAb binds solely to the intracellular myosin that is exposed on cell death, Myoscint concentrates only in necrotic cells. It therefore permits precise localization of unsalvageable tissue.

Improved MI diagnosis may result

Myoscint (antimyosin) may permit MI detection and localization in situations that may otherwise be difficult to interpret. A recent study demonstrates the potential utility of Myoscint imaging. A 73-year-old female patient with unstable angina pectoris underwent coronary angiography which revealed an 80% diameter stenosis of the left anterior descending coronary artery and a 35% lesion of the left circumflex coronary artery. Because of continued symptoms, percutaneous transluminal coronary angioplasty (PTCA) was performed and resulted in successful revascularization. Twenty-four hours later, she developed severe chest pain and electrocardiographic changes consistent with an acute myocardial infarction. The subsequent clinical course was uncomplicated, and the creatine kinase level peaked at 840 IU, with a positive MB fraction.

Indium-111 labeled Myoscint was injected without incident approximately 48 hours after onset of chest pain. Serial images were obtained thereafter at 17 and 41 hours post antimyosin injection. Initial planar imaging (shown in the accompanying figure in the left anterior oblique position) demonstrated a large area of intense radiotracer uptake in the anteroseptal region. Subsequent tomographic images confirmed the extensive area of anteroseptal myocardial necrosis. Tomographic thallium-201 imaging (shown in the accompanying figure in the vertical long axis orientation) was performed several days later and demonstrated a moderate-sized perfusion defect, corresponding in location to the area of necrosis on the indium-111 Myoscint image. Pre-discharge left ventricular ejection fraction obtained by radionuclide angiocardiography was 38%.

This patient example demonstrates the ability of indium-111 labeled Myoscint to document and localize myocardial necrosis in a patient with unstable ischemic heart disease. The Myoscint study clearly documented an extensive area of irreversible damage and helped differentiate scar from transient myocardial ischemia.

Ongoing Myoscint research

Myoscint is being evaluated extensively in conjunction with traditional imaging techniques, including early thallium-201 imaging, contrast ventriculography, and gated radionuclide angiography (wall motion studies). This research continues to verify Myoscint's efficacy for identifying zones of acute myocardial necrosis.

Available for investigational use

Myoscint is now available for investigational use only. If you would like more information on this product, or other biotechnological products under development at Centocor, please call us, toll free.

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DPA/QCT COMPARISON

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<thead>
<tr>
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<th>DPA</th>
<th>QCT</th>
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<tbody>
<tr>
<td>Marrow Dose</td>
<td>2 mrem</td>
<td>1000 mrem</td>
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<tr>
<td>Cost</td>
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<td>Sites</td>
<td>Several</td>
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<tr>
<td>Accuracy</td>
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<tr>
<td>Interscanner Variation</td>
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<td>Patient Acceptance</td>
<td>Good</td>
<td>Fair</td>
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*Images obtained with the University of Texas TOFPET (11mm x 11mm resolution).
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**CLINICAL EXAMPLE**

Transaxial 2-D image planes of Myocardial perfusion in patient with anterior infarct.

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Same data converted into 3-D surface displays of Myocardial perfusion. Green areas show infarcted zones, caused by a mid LAD lesion.

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Early and accurate diagnosis of neurological diseases is one of the prime responsibilities of major referral centers worldwide. Neurological diseases such as Stroke, TIA, Epilepsy, and Dementia already impose crippling in-patient financial burdens on most hospitals. This trend is moving upwards, especially due to the aging population. Today the availability of new perfusion and receptor-site-specific radiopharmaceuticals, specifically developed for Neuro-SPECT imaging, offer opportunities for accurate diagnosis and treatment unknown until now.

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Please see adjacent page for brief summary.
DESCRIPTION
Macrotec is a sterile, nonpyrogenic, lyophilized preparation of albumin aggregated. Each 5 ml vial of Macrotec contains 1.5 mg of Technetium Tc 99m Albumin Aggregated, 10.0 mg Albumin Human, 0.07 mg (minimum) stannous chloride (SnCl2·2H2O) and 0.19 mg total tin, maximum (as stannous chloride, SnCl2·2H2O), 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 6.0.

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 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 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 into the syringe, 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).
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The Society of Nuclear Medicine

ORGANIZATION
The Society of Nuclear Medicine (SNM) is a multi-disciplinary organization of physicians, physicists, chemists, radiopharmacists, technologists, and others interested in the diagnostic, therapeutic, and investigational use of radiopharmaceuticals. Founded in Seattle, Washington in 1954, it is the largest scientific organization dedicated to nuclear medicine.

OBJECTIVES
Maintain an organization supported by professionals of varied backgrounds who have a common interest in the clinical and scientific discipline of nuclear medicine;
Hold meetings and seminars to communicate new knowledge acquired and provide continuing medical education;
Advance the highest standards in the practice of nuclear medicine;
Disseminate information by means of journals, books, monographs, and audiovisuals;
Promote and maintain the highest standards of education and research.

BENEFITS OF MEMBERSHIP

The Journal of Nuclear Medicine: a subscription to the official publication of The Society of Nuclear Medicine and the most prominent journal in the field. Published monthly, it provides the membership with up-to-date information on current developments in nuclear medicine.

Annual Meetings: discounts to scientific, clinical, and continuing education presentations, as well as commercial exhibits, to keep abreast of the latest developments.

Membership Directory: distributed biennially, at no extra cost, to the entire membership.

Books and Monographs: discounts on selected new topics published by the Society.

Audiovisuals: discounts on slide/tape programs covering a wide variety of subjects designed for classroom use and self-instruction.

Pamphlets: on a number of topics including how to present scientific papers and how to prepare scientific exhibits.

Awards: presented to Society members for outstanding achievements and contributions to the field.

Continuing Education Credit: for meeting courses, audiovisuals, and exhibits, approved for AMA Category 1 credit.

Research and Fellowship Support: through SNM Education and Research Foundation.

Effective Government Relations: through committees and lobbying efforts.

Insurance Plans: disability income, and catastrophic major medical insurance programs.

Car Rental: discounts on Avis car rentals.

Credit Cards: Visa and MasterCard are available to eligible members.

SNM COUNCILS
To satisfy the needs of those individual disciplines within nuclear medicine, the Society has established special interest Councils that function autonomously within the Society and are open to all interested Society members: Academic, Cardiovascular, Computer, Correlative Imaging, Instrumentation, Radioassay, and Radiopharmaceutical Science.

The ACADEMIC COUNCIL is composed of faculty members of nuclear medicine departments, divisions, or sections in accredited nuclear medicine schools, or those in AMA approved nuclear medicine residency programs in the U.S. or Canada.

The objectives of the Council are: (1) to promote medical education, research, and patient care related to nuclear medicine; (2) to develop better methods of undergraduate and graduate teaching of nuclear medicine; and (3) to provide a forum for discussion of problems of mutual interest and concern, as well as an informal exchange of ideas and programs. Within the Council there is a sub-group of directors of nuclear medicine residency training programs who confer at least annually with the ABNM on areas of mutual interest.

The CARDIOVASCULAR COUNCIL consists of Society members interested in the performance and application of cardiovascular nuclear medicine procedures. It seeks to provide a forum for discussion and development of cardiac scintigraphic methods in an effort to realize the most beneficial applications. The Council actively seeks individuals who share this goal.

The COMPUTER COUNCIL is made up of Society members who have an interest in computers and their application in the diagnostic, therapeutic, and investigative areas of nuclear medicine. It provides a source of information relating to computer science to the Society membership through its meetings and publications.

The CORRELATIVE IMAGING COUNCIL provides a structure in which clinicians and scientists can develop and disseminate information on the medical and physiological applications of various imaging modalities as they correlate to nuclear medicine.

The INSTRUMENTATION COUNCIL promotes the advancement and dissemination of knowledge of instrumentation utilized in nuclear medicine and serves as a resource center in instrumentation for the Society.

The RADIOASSAY COUNCIL maintains the scientific, economic, and historic elements of the radioassay discipline within the Society.

The RADIOPHARMACEUTICAL SCI-ENCE COUNCIL provides a forum for discussion and dissemination of information relating to the radiopharmaceutical sciences and promotes and encourages basic radiopharmaceutical research and development within the Society. It publishes a newsletter and holds periodic meetings on special subjects.

For further information please contact:

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Nuclear Imaging in Oncology
E. Edmund Kim, M.D. and Thomas P. Haynie, M.D.
An overview of various imaging studies for cancers in different organ systems, this volume also correlates and compares the diagnostic accuracy of these various radiologic imaging modalities.
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Skeletal Imaging
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<td>Squibb Diagnostics</td>
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<td>New Brunswick, NJ</td>
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<td>Sudbury Systems, Inc.</td>
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<td>Viott Corporation</td>
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<td>Seattle, WA</td>
<td>63A</td>
<td>51</td>
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If you're looking for the best uptake system, designed for patient comfort and easy operation, take a look at the Thyroid Uptake System II from Atomic Products.

It sets new performance standards because it is "truly dedicated" to thyroid uptake activity studies.

Operation is simple, and straightforward, thanks to the user friendly menu selection and logical control panel design. All operations and calculations are handled by a high-speed microprocessor with data displayed on the built-in video monitor. An optional printer is available for hard copy.

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**Circle one answer in each category.**

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<th>SNM Member</th>
<th>Reason for Inquiry</th>
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INDICATION AND USAGE: Thallous Chloride TI 201 may be used in cardiac imaging to define the extent of myocardial infarction. It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

CONTRAINDICATIONS: None known.

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

PRECAUTIONS

General
Do not use after the expiration time and date (4 days after calibration time) stated on the label.
Discard vial after single use. Do not use if contents are turbid.
The patient dose should be measured by a suitable radiotracery activity measurement device immediately prior to administration.
Ideally, examinations using radiopharmaceuticals, especially those effective in nature on a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Pediatric Use
Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Adverse reactions related to use of this agent have not been reported to date.

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