STUDY TITLE: 
ERASE (Emergency Room Assessment of Sestamibi for the Evaluation of Chest Pain)

PUBLICATION TITLE:
Myocardial Perfusion Imaging for Evaluation and Triage of Patients with Suspected Acute Cardiac Ischemia

JOURNAL:
Journal of the American Medical Association 2002: 288:21; 2693-2700

AUTHORS:
Udelson JE, Beshansky JR, Ballin DS, et al.

CONTEXT: Observational studies of acute myocardial perfusion imaging in emergency department (ED) patients with chest pain have suggested high sensitivity and negative predictive value for acute cardiac ischemia, but use of this method has not been prospectively tested.

OBJECTIVE: To assess whether incorporating acute resting perfusion imaging into an ED evaluation strategy for patients with suspected acute ischemia but no initial electrocardiogram (ECG) changes diagnostic of acute ischemia improves clinical decision making.

DESIGN, SETTING AND PATIENTS: The ERASE (Emergency Room Assessment of Sestamibi for the Evaluation of Chest Pain) study was a prospective, randomized controlled trial conducted at 7 academic medical centers and community hospitals between July 1997 and May 1999 among 2,475 adult ED patients with chest pain or other symptoms suggestive of acute cardiac ischemia and with normal or nondiagnostic initial ECG results.

INTERVENTION: Patients were randomly assigned to receive either the usual ED evaluation strategy (n=1,260) or the usual strategy supplemented with results from acute resting myocardial perfusion imaging using single photon emission computed tomography with injection of 20 to 20 mCi of Tc-99m sestamibi (n=1,215), interpreted in real time by local staff physicians and with results provided to the ED physician for incorporation into clinical decision making.

MAIN OUTCOME MEASURE: Appropriateness of triage decision either to admit to hospital/observation or to discharge directly home from the ED.

CARDIOLITE® UTILIZATION: Cardiolite® was the myocardial perfusion imaging agent selected for use in the ERASE study. 1,215 patients were randomized to undergo a resting myocardial perfusion imaging study with Cardiolite® as part of the usual ED evaluation strategy.

RESULTS: Among patients with acute cardiac ischemia (i.e., acute myocardial infarction (MI) or unstable angina; n=329), there were no differences in ED triage decisions between those receiving standard evaluation and those whose evaluation was supplemented by a sestamibi scan. Among patients with acute MI (n=56), 97% vs. 96% were hospitalized (relative risk [RR], 1.00; 95% confidence interval [CI], 0.89-1.12), and among those with unstable angina (n=273), 83% were hospitalized (RR, 0.98); 95% CI, 0.87-1.10). However, among patients without acute cardiac ischemia (n=2146), hospitalization was 52% with usual care vs. 42% with sestamibi imaging.

CONCLUSIONS: Sestamibi perfusion imaging improves ED triage decision making for patients with symptoms suggestive of acute cardiac ischemia without obvious abnormalities on initial ECG. In this study, unnecessary hospitalizations were reduced among patients without acute ischemia, without reducing appropriate admission for patients with acute ischemia.
**INDICATIONS AND USAGE FOR CARDIOLITE®:**

Indications and Usage Cardiolite®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, is a myocardial perfusion agent that is indicated for detecting coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects), in evaluating myocardial function and developing information for use in patient management decisions. Cardiolite® evaluation of myocardial ischemia can be accomplished with rest and cardiovascular stress techniques (e.g., exercise or pharmacologic stress in accordance with the pharmacologic stress agent's labeling).

It is usually not possible to determine the age of a myocardial infarction or to differentiate a recent myocardial infarction from ischemia.

**IMPORTANT SAFETY INFORMATION FOR CARDIOLITE:**

Exercise and pharmacologic stress testing should be performed only under the supervision of a qualified physician. Cardiolite® has been rarely associated with acute severe allergic events of angioedema and urticaria. The most frequently reported adverse events include headache, chest pain/angina, ST segment changes on ECG, nausea, and abnormal taste and smell.
CARDIOLITE®
Kit for the Preparation of Technetium Tc99m Sestamibi for Injection

FOR DIAGNOSTIC USE

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use CARDIOLITE® safely and effectively. See full prescribing information for CARDIOLITE®

CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection. Initial U.S. Approval: December, 1990

--- RECENT MAJOR CHANGES ---
Use in specific populations (8.3)

10/2007

--- INDICATIONS AND USAGE ---
CARDIOLITE® is a myocardial perfusion agent indicated for:
• Detecting/coronary artery disease by localizing myocardial ischemia (reversible defects) and infarction (non-reversible defects)
• Evaluating myocardial function and developing information for use in patient management decisions

--- DOSAGE AND ADMINISTRATION ---
• For Myocardial Imaging: The suggested dose range for IV administration of CARDIOLITE® in a single dose to be employed in the average patient (70 Kg is 370 - 1110 MBq (10 - 30 mCi)).
• For Breast Imaging: The recommended dose range for IV administration of MIRALUMA® is a single dose of 740 - 1110 MBq (20 - 30 mCi).

--- DOSAGE FORMS AND STRENGTHS ---
• CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection is supplied as a lyophilized mixture in a 5 ml vial.

--- CONTRAINDICATIONS ---
None known

--- WARNINGS AND PRECAUTIONS ---
• Pharmacologic induction of cardiovascular stress may be associated with serious adverse events such as myocardial infarction, arrhythmia, hypotension, myocardial necrosis and cerebrovascular events.
• CARDIOLITE® has been rarely associated with severe allergic and anaphylactic events of angioedema and generalized urticaria. In some patients the allergic symptoms developed on the second injection during CARDIOLITE® imaging.
• Caution should be exercised and emergency equipment should be available when administering CARDIOLITE®.
• Before administering CARDIOLITE®, patients should be asked about the possibility of allergic reactions to either drug.

--- ADVERSE REACTIONS ---
• The following adverse reactions have been reported in ≤ 0.5% of patients: signs and symptoms consistent with those occurring shortly after administration of the agent; transient arthralgia, myalgia, anxiety, rhinorrhea, urticaria, sweating, myalgia, and cardiovascular events.

--- DRUG INTERACTIONS ---
• Specific drug-drug interactions have not been studied.

--- USE IN SPECIFIC POPULATIONS ---
• In one study of 46 subjects who received CARDIOLITE® administration, the radiotracer in both children and adolescents exhibited blood PK profiles similar to those previously reported in adults.

See 17 FOR PATIENT COUNSELING INFORMATION

Revised: May 2014

FULL PRESCRIBING INFORMATION: CONTENTS:*

1. INDICATIONS AND USAGE
2. DOSAGE AND ADMINISTRATION
3. DOSAGE FORMS AND STRENGTHS
4. CONTRAINDICATIONS
5. WARNINGS AND PRECAUTIONS
6. ADVERSE REACTIONS
7. DRUG INTERACTIONS
8. USE IN SPECIFIC POPULATIONS
9. PEDiatric Use
10. OVERDOSAGE
11. DESCRIPTION
12. CLINICAL PHARMACOLOGY
13. STUDIES
14. REFERENCES
15. HOW SUPPLIED/STORAGE AND HANDLING
16. PATIENT COUNSELING INFORMATION

--- Table 1.0 ---
Table 1.0. Radiation Absorbed Doses from Tc99m Sestamibi

<table>
<thead>
<tr>
<th>Organ</th>
<th>30 mCi</th>
<th>1110 MBq</th>
<th>30 mCi</th>
<th>1110 MBq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breasts</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Gallbladder Wall</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
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<tr>
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<td>3.0</td>
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<tr>
<td>Upper Large Intestine</td>
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<td>40.0</td>
<td>4.2</td>
<td>41.1</td>
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<td>6.1</td>
<td>0.6</td>
<td>5.8</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>5.1</td>
<td>0.5</td>
<td>4.9</td>
</tr>
<tr>
<td>Kidneys</td>
<td>2.0</td>
<td>20.0</td>
<td>2.0</td>
<td>20.0</td>
</tr>
<tr>
<td>Liver</td>
<td>0.6</td>
<td>5.8</td>
<td>0.6</td>
<td>5.7</td>
</tr>
<tr>
<td>Lungs</td>
<td>0.3</td>
<td>2.8</td>
<td>0.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Bone Surfaces</td>
<td>0.7</td>
<td>6.8</td>
<td>0.7</td>
<td>6.4</td>
</tr>
<tr>
<td>Thyroid</td>
<td>0.7</td>
<td>7.0</td>
<td>0.7</td>
<td>7.0</td>
</tr>
<tr>
<td>Ovaries</td>
<td>1.5</td>
<td>15.5</td>
<td>1.5</td>
<td>15.5</td>
</tr>
<tr>
<td>Testes</td>
<td>0.3</td>
<td>3.4</td>
<td>0.3</td>
<td>3.4</td>
</tr>
<tr>
<td>Red Marrow</td>
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<td>4.4</td>
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<tr>
<td>Urinary Bladder Wall</td>
<td>2.0</td>
<td>20.0</td>
<td>2.0</td>
<td>20.0</td>
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</table>

--- Table 1.0 ---
2.0 hour void 4.8 hour void

<table>
<thead>
<tr>
<th>Organ</th>
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<th>1110 MBq</th>
<th>30 mCi</th>
<th>1110 MBq</th>
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<td>Breasts</td>
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<td>0.2</td>
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<tr>
<td>Gallbladder Wall</td>
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<td>27.8</td>
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<tr>
<td>Small Intestine</td>
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<td>24.4</td>
<td>2.4</td>
<td>24.4</td>
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<tr>
<td>Upper Large Intestine</td>
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<td>44.5</td>
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<td>44.5</td>
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<td>Wall</td>
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<td>32.2</td>
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<tr>
<td>Stomach Wall</td>
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<td>5.3</td>
<td>0.5</td>
<td>5.2</td>
</tr>
<tr>
<td>Heart Wall</td>
<td>0.5</td>
<td>5.6</td>
<td>0.5</td>
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<tr>
<td>Kidneys</td>
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<td>16.7</td>
<td>1.7</td>
<td>16.7</td>
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<tr>
<td>Liver</td>
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<tr>
<td>Lungs</td>
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<td>2.6</td>
<td>0.3</td>
<td>2.4</td>
</tr>
<tr>
<td>Bone Surfaces</td>
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<td>6.2</td>
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<td>6.0</td>
</tr>
<tr>
<td>Thyroid</td>
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<td>2.7</td>
<td>0.2</td>
<td>2.4</td>
</tr>
<tr>
<td>Ovaries</td>
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<td>12.2</td>
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<td>13.3</td>
</tr>
<tr>
<td>Testes</td>
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<td>3.1</td>
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<td>3.4</td>
</tr>
<tr>
<td>Red Marrow</td>
<td>0.5</td>
<td>4.6</td>
<td>0.5</td>
<td>4.4</td>
</tr>
<tr>
<td>Urinary Bladder Wall</td>
<td>1.5</td>
<td>15.5</td>
<td>3.0</td>
<td>30.0</td>
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<tr>
<td>Total Body</td>
<td>0.5</td>
<td>4.8</td>
<td>0.5</td>
<td>4.8</td>
</tr>
</tbody>
</table>


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

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support equipment.

The most frequent exercise stress test endpoints sufficient to stop the test during controlled studies (two-thirds were cardiac patients): were:

- Fatigue 35%
- Dyspnea 17%
- Chest Pain 16%
- Bradycardia, tachycardia, T-depression
- Arthritism 1%

6. ADVERSE REACTIONS

Adverse events were evaluated in 3741 adults who were evaluated in clinical studies. Of these patients, 3068 (77% men, 22% women, and 0.7% of the patients' genders were not recorded) were in cardiac clinical trials and 673 (100% women) in breast imaging trials. Cases of angina, chest pain, and death have occurred (see Section 5). Adverse events reported at a rate of 0.5% or greater after receiving Technetium Tc99m Sestamibi administration are shown in the following tables.

7. DRUG INTERACTIONS

Specific drug-drug interactions have not been studied.

8. USE IN SPECIFIC PATIENTS

8.1 Pregnancy

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is also not known whether Technetium Tc99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

Technetium Tc99m Sestamibi is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

8.4 Pediatric Use

Safety and effectiveness in the pediatric population have not been established. No evidence of diagnostic efficacy or clinical utility of CARDIOLITE® scan was found in clinical studies of children and adolescents with Kawasaki disease. A prospective study of 445 pediatric patients with Kawasaki disease was designed to determine the predictive value of CARDIOLITE® rest and stress myocardial perfusion imaging to define a pediatric population with Kawasaki disease that was at risk of developing cardiac events. Cardiac events were defined as cardiac death, MI, hospitalization due to cardiac etiology, heart failure, CABG or coronary angioplasty. The standard of truth was defined as cardiac events occurring 6 months following the administration of CARDIOLITE®. Only three cardiac events were observed at six months in this study. In all three cases, the scan was negative. No clinically meaningful measurements of sensitivity, specificity or other diagnostic performance parameters could be demonstrated in this study.

A ten year retrospective case history study of pediatric Kawasaki disease patients who completed CARDIOLITE® myocardial perfusion imaging and who had coronary angiography within three months of the CARDIOLITE® scan was designed to measure sensitivity and specificity of CARDIOLITE® scan. Out of 72 patients who had both evaluable CARDIOLITE® scans and evaluable angiographic images, only one patient had both an abnormal angiogram and an abnormal CARDIOLITE® scan. No clinically meaningful measurements of sensitivity, specificity or other diagnostic performance parameters could be demonstrated in this study.

In a clinical pharmacology study, 46 pediatric patients with Kawasaki disease received CARDIOLITE® administration at the following doses: 0.1 – 0.2 mCi/kg for rest, 0.3 mCi/kg for stress in one day studies; 0.2 mCi/kg for rest and 0.2 mCi/kg for stress in two day studies.

The radioactivity in both younger children and in adolescents exhibited PK profiles similar to those previously reported in adults (See Section 12).

The radiation absorbed doses in adolescents, both at rest and stress, were similar to those observed in adults (see Section 2). When comparing weight-adjusted radioactivity (up to 0.3 mCi/kg) doses administered to adolescents and younger children to the recommended dose administered to adults (up to 0.3 mCi/kg), the radiation absorbed doses in both adolescents and younger children were similar to those in adults.

Adverse events were evaluated in 609 pediatric patients from the three clinical studies described above. The frequency and the type of the adverse events were similar to the ones observed in the studies of CARDIOLITE® in adults. Two of the 609 had a serious adverse event: one patient received a CARDIOLITE® overdose but remained asymptomatic, and one patient had an asthma exacerbation following administration.

9.5 Geriatric Use

Of 3068 patients in clinical studies of CARDIOLITE®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, 693 patients were 65 or older and 121 were 75 or older.

Of 673 patients in clinical studies of MIRALUMA®, Kit for the Preparation of Technetium Tc99m Sestamibi for Injection, 138 patients were 65 or older and 30 were 75 or older.

Based on the evaluation of the frequency of adverse events and review of vital signs data, no overall differences in safety were observed between these subjects and younger subjects. Although reported clinical experience has not identified differences in response between elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out.

9.6 DRUG ABUSE AND DEPENDENCE

9.6.1 Substance Not applicable.

9.6.2 Abuse Not applicable.

9.6.3 Dependence Not applicable.

9.7 OVERDOSAGE

The clinical consequences of overdosing with CARDIOLITE® are not known.

11. DESCRIPTION

Each 5 mL vial contains a sterile, non-pyrogenic, lyophilized mixture of:

- Tetrofosmin (2-methoxy isobutyl iodide) Copper (II) tetrafluoroborate -1 mg
- Sodium Citrate Dihydrate -2.6 mg
- L-Cysteine Hydrochloride Monohydrate -1.0 mg
- Mannitol -7.5 mg
- Stannous Chloride, Dihydrate, minimum (SnCl2·2H2O) -0.075 mg
- Stannous Chloride, Dihydrate, maximum (SnCl2·2H2O) -0.096 mg
- Sodium Chloride (stannous) stannic fluoride, maximum (as SnCl2·2H2O) -0.017 mg

Prior to lyophilization the pH is 5.3 to 5.9. The contents of the vial are lyophilized and stored under nitrogen.

11.2 Externally Radiated

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxidant-free Sodium Pertechnetate Tc99m Injection. The pH of the reconstituted product is 5.5 (5.0 - 6.0). No bacteriostatic preservative is present.

The precise structure of the technetium complex is Tc99m(MIBI)⁺, wherein MIBI is 2-methoxy isobutyl isonitrile.

11.1 Physical Characteristics

Technetium Tc99m decays by isomeric transition with a physical half-life of 6.02 hours. Photons that are useful for detection and imaging studies are listed below in Table 5.0.

Table 5.0. Radiopharmaceutical Data

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tc99m (MBIS)</td>
<td>0.0175 mg</td>
</tr>
<tr>
<td>Tc99m (MBIS)</td>
<td>0.025 mg</td>
</tr>
<tr>
<td>Tc99m (MBIS)</td>
<td>0.035 mg</td>
</tr>
<tr>
<td>Tc99m (MBIS)</td>
<td>0.15 mg</td>
</tr>
<tr>
<td>Tc99m (MBIS)</td>
<td>0.25 mg</td>
</tr>
<tr>
<td>Tc99m (MBIS)</td>
<td>0.30 mg</td>
</tr>
</tbody>
</table>

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals after the time of calibration are shown in Table 5.0.
EVALUATED IN 521 PATIENTS (511 MEN, 10 WOMEN) WITH STABLE CHEST PAIN. THERE WERE

CLINICAL TRIALS:

MICRONUCLEUS TEST AT A DOSE WHICH CAUSED SYSTEMIC AND BONE MARROW TOXICITY (9 MG/ML

LYMPHOCYTE ASSAY. Cu(MIBI)

SISTER CHROMATID EXCHANGE TESTS (ALL IN VITRO). AT CYTOTOXIC CONCENTRATIONS (> 20 µG/ML),

THE BATTERY OF FIVE TESTS. NO GENOTOXIC ACTIVITY WAS OBSERVED IN THE AMES, CHO/HPRT AND

BREAST IMAGING: MIRALUMA® WAS EVALUATED IN TWO MULTICENTER, CLINICAL TRIALS OF A TOTAL OF 673 WOMEN PATIENTS. OVERALL THE MEAN AGE WAS 52 (RANGE 23 TO 87 YEARS). THE RACIAL AND ETHNIC REPRESENTATION WAS 70.2% CAUCASIAN, 24.2% BLACK, 5.1% ASIAN, 0.5% HISPANIC. BOTH CLINICAL STUDIES WERE DESIGNED TO ASSESS THE RADIOLOGIC PERFORMANCE OF MIRALUMA® FOR THE DETECTION OF BREAST MALIGNANCY IN PATIENTS WITH DOSING UNDER WAY TO THE APPEARANCE OF A TUMOR (E.G., BENIGN, INFLAMMATORY, MALIGNANT, FIBROUS) HAS NOT BEEN ESTABLISHED.

MICROCYCLIC BLOOD POOL CATHODE RAY OSCILLOSCOPE (A SPECIFIC SENSITIVITY FOR THE DETECTION OF MALIGNANCY). THE CLINICAL USEFULNESS OF A POSITIVE MIRALUMA® IMAGE IN THE ABSENCE OF AN ABNORMAL MAMMOGRAM OR ABNORMAL LESION IS NOT KNOWN.

REFERENCES:

Not applicable.

15. HOW SUPPLIED/STORAGE AND HANDLING

CARDIOXIL® KIT FOR THE PREPARATION OF TECHNETIUM Tc99M SPECTRUM FOR INJECTION IS SUPPLIED AS A 5 ML VIAL IN KITS OF FIVE (5) VIALS (NDC # 11994-001-55) AND TWENTY (20) VIALS (NDC # 11994-001-20), STERILE AND NON-PYOGENIC.

THE PATIENT DOSE SHOULD BE MEASURED BY A RADIOACTIVITY CALIBRATION SYSTEM IMMEDIATELY PRIOR TO PATIENT ADMINISTRATION. RADIOCHEMICAL PURITY SHOULD BE CHECKED PRIOR TO PATIENT ADMINISTRATION.

PARENTERAL DRUG PRODUCTS SHOULD BE INSPECTED VISUALLY FOR PARTICULATE MATTER AND DISCOLORATION PRIOR TO ADMINISTRATION WHENEVER SOLUTION AND CONTAINER PERMIT.

PRIOR TO HYPOXIZATION THE pH IS BETWEEN 5.3-5.9. THE CONTENTS OF THE VIALS ARE STABILIZED AND STORED UNDER NITROGEN. STORE AT 15-25°C (59-77°F) BEFORE AND AFTER RECONTAINMENT.

TECHNETIUM Tc99M SPECTRUM CONTAINS NO PRESERVATIVES. INCLUDED IN EACH FIVE (5) VIAL KIT IS ONE (1) PACKAGE INSERT, TWO (2) VIAL SEAL LABELS AND SIX (6) RADIATION WARNING LABELS. INCLUDED IN EACH TWENTY (20) VIAL KIT IS ONE (1) PACKAGE INSERT, TWENTY FOUR (24) VIAL SEAL LABELS AND TWENTY FOUR (24) RADIATION WARNING LABELS. THIS REAGENT KIT IS APPROVED FOR DISTRIBUTION TO PERSONS LICENSED PURSUANT TO THE CODE OF FEDERAL REGULATIONS 100 CFR 120.500 FOR THE USES LISTED IN 100 CFR 120.547 OR 120.552, OR UNDER EQUIVALENT REGULATIONS OF THE U.S. NUCLEAR REGULATORY COMMISSION, AGREEMENT STATES OR LICENSING STATES.

17. PATIENT COUNSELING INFORMATION

CARDIOXIL® AND MIRALUMA® ARE DIFFERENT NAMES FOR THE SAME DRUG. PATIENTS SHOULD BE ADVISED TO INFORM THEIR HEALTHCARE PROVIDER IF THEY HAVE AN ALLERGIC REACTION TO EITHER DRUG OR IF THEY HAVE AN ALLERGIC REACTION TO EITHER DRUG OR IF THEY HAD AN ALLERGIC REACTION TO EITHER DRUG OR IF THEY HAD AN ALLERGIC REACTION TO EITHER DRUG OR IF THEY HAD AN ALLERGIC REACTION TO EITHER DRUG.