1.3.1.1 PACKAGE INSERT

SCHEDULING STATUS: **S3**

PROPRIETARY NAME **ST THOMAS' HOSPITAL CARDIOPLEGIC SOLUTION II**

(and dosage form): Solution

COMPOSITION:

Each 1000 ml contains:

Calcium Chloride (Dihydrate)	0,175 g
Sodium Chloride	6,42 g
Potassium Chloride	1,19 g
Magnesium Chloride (Hexahydrate)	3,25 g
Water for Injections	QS

ST THOMAS' HOSPITAL CARDIOPLEGIC SOLUTION II is mixed aseptically with 10 ml of 8,5 % sodium bicarbonate before use. 3,6 ml of a 50 % glucose injection may be added if required.

The final measured osmolality of the solution after the addition of glucose and sodium bicarbonate is approximately 323 milliosmoles/kg.

PHARMACOLOGICAL CLASSIFICATION:

A.24 (Mineral substitutes, electrolytes).

INDICATIONS:

Use as a cardioplegic solution.

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CONTRA-INDICATIONS:

It is recommended that cardioplegia is not administered to patients currently on Amioderone therapy. Amioderone should be discontinued for a minimum of six weeks prior to cardiac surgery.

WARNINGS and SPECIAL PRECAUTIONS:

1. Solutions containing sodium should be used with great care in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists oedema with or without sodium retention.
2. Solutions containing potassium ions should be used with great care in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.
3. Solutions containing calcium ions should not be administered through the same administration set as blood anticoagulated with calcium chelators, e.g. Anticoagulants, Citrate, Glucose or Citrate Phosphate Glucose, because of the likelihood of coagulation.
4. The intravenous administration of these solutions can cause fluid and/or solute overloading, resulting in dilution of serum concentrations, overhydration, congested states and/or pulmonary oedema.
5. Additives may be incompatible. Consult with pharmacist, if necessary, to ensure compatibility of prescribed additives. When introducing additives, use aseptic technique. Mix thoroughly when additives have been introduced.
6. Do not store solutions containing additives for more than 24 hours.
   Do not administer unless the solution is clear and the container is intact.

DOSAGE AND DIRECTIONS FOR USE:

Before use mix with 10 ml of 8,5% sodium bicarbonate and if required 3,6 ml of 50% glucose injection. An induction dose of 10 - 20 ml/kg of ST THOMAS' HOSPITAL CARDIOPLEGIC SOLUTION II should be

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infused into the coronary circulation immediately after aortic clamping in order to effect rapid electro-mechanical arrest. Thereafter multidose cardioplegia 5 - 10 ml/kg, is reinfused every 20 - 30 minutes throughout the ischaemia cross clamp period. The solution is infused under positive pressure, and it is recommended that the infusion pressure (measured at the aortic root) should not exceed 100 mmHg.

The solution should be infused at a temperature of 4 °C to 10 °C. It is recommended that an in-line cardioplegic filter of at least 0,8 micron is used.

SIDE EFFECTS:

Reactions which may occur because of the solution or the technique of administration include febrile response, extravasation and hypervolemia.

Pregnancy:

Safety in pregnancy has not been established.

IDENTIFICATION:

A clear, colourless solution.

PRESENTATION:

ST THOMAS' HOSPITAL CARDIOLOGIC SOLUTION II is available in 1000 ml Viaflex® containers and 1000ml Vacollter® Containers.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

After mixing, the solution should be refrigerated (2 °C - 8 °C) and the unused portion discarded after 24 hours. Keep out of reach of children.

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REGISTRATION NUMBER:

Z/24/2

NA: NS2 04/24/1664

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

ADCOCK INGRAM CRITICAL CARE (PTY) LTD

1 Sabax Road

Aeroton

Johannesburg

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