



SPY Elite™ Pack and SPY Elite™ Kit

Instructions for Use



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SPY *Elite*™ Pack and SPY *Elite*™ Kit

Instructions for Use

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. The contents of the SPY *Elite*™ Pack (LC3006 and LC3012) and single patient use SPY *Elite*™ Kit (LC3001 and LC3002) must only be used with the SPY *Elite*™ Device (LC3000). The SPY *Elite*™ Device and the SPY *Elite*™ Kit make up the SPY *Elite*™ System.

INDICATIONS FOR USE

The SPY *Elite*™ Kit is indicated for use with the SPY *Elite*™ Device.

The SPY *Elite*™ System is an imaging system used in capturing and viewing fluorescence images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

The SPY *Elite*™ System is intended to provide fluorescence images for the visual assessment of blood flow in vessels and related tissue perfusion during gastrointestinal surgical procedures.

DESCRIPTION of the SPY *Elite*™ Kit and SPY *Elite*™ Pack

Each SPY *Elite*™ Pack contains six (6) SPY *Elite*™ Kits.

Each LC3006 contains six SPY *Elite*™ Single-Vial Kits (LC3001) each with one (1) 25 mg vial of ICG imaging agent, one (1) 10 ml vial Water for Injection and one (1) SPY *Elite*™ Sterile Drape.

Each LC3012 contains six (6) SPY *Elite*™ Double-Vial Kits (LC3002) each with two (2) 25 mg vials of ICG imaging agent, two (2) 10 ml vials Water for Injection and one (1) SPY *Elite*™ Sterile Drape.

The contents of the SPY *Elite*™ Kit must only be used with the SPY *Elite*™ Device.

The use of the SPY *Elite*™ Kit must be in accordance with the SPY *Elite*™ Kit Instructions for Use or SPY *Elite*™ Operator's Manual provided with the System.

The individual contents of SPY *Elite*™ Kit are for single use only. Do **NOT** re-use or re-sterilize any of the individual components of the SPY *Elite*™ Kit.

The SPY *Elite*™ Pack, the SPY *Elite*™ Kit, the packaging for the SPY *Elite*™ Sterile Drape and the outside of the vials are **not** sterile. The inner contents of each of the components of the SPY *Elite*™ Kits are supplied sterile.

The SPY *Elite*™ Kit should only be used by physicians or under the supervision of physicians experienced in techniques of microvascular surgery.

ICG

ICG is a sterile, water soluble, tricarboyanine dye with a peak spectral absorption at 800-810 nm, in blood plasma or blood. Note that endogenous species have low light absorption in that range. ICG contains not more than 5.0% sodium iodide. ICG is to be administered intravenously.

The Water for Injection provided with the ICG, pH of 5.0 to 7.0, is used to dissolve the ICG.

Before injection of ICG for each patient's imaging procedure, the ICG must be reconstituted using the Water for Injection.

THE SPY ELITE™ STERILE DRAPE

The SPY *Elite*™ Sterile Drape is a custom sterile surgical drape that attaches to the SPY *Elite*™ Device via a specially designed optical window and sterile tapes, and is designed to maintain sterility of the device's articulating arm throughout the procedure.

ICG CHARACTERISTICS

Clinical Pharmacology

Following intravenous injection, ICG is rapidly bound to plasma proteins, primarily lipoproteins with a lesser and variable binding

to albumin (2-30% of total). Simultaneous arterial and venous blood estimations have shown negligible renal, peripheral, lung or cerebro-spinal uptake of the dye. ICG is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is secreted entirely into the bile. ICG does not undergo significant enterohepatic recirculation. ICG has a half-life of 2.5 - 3.0 minutes.

Drug/drug interaction studies have not been performed.

Optical Attributes in blood

Maximum absorption (in blood) at 806 nm

Peak emission wavelength : 830 nm

Maximum fluorescence in concentration range
4 - 10 µg/ml

Contraindications/Warnings/Precautions/Adverse Reactions

The following safety information focuses on the components of the SPY *Elite*™ Kit. For full SPY *Elite*™ System safety information, please refer to the SPY *Elite*™ Operator's Manual that is provided with the System.

The contraindications, warnings, precautions and adverse events for the SPY *Elite*™ Kit are divided into two sections: the first section pertains to ICG, the second is related to the SPY *Elite*™ Sterile Drape.

ICG

Contraindications

ICG contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides or iodinated contrast agents.

The SPY *Elite*™ System should not be used during surgical procedures with patients who are known to be sensitive to iodides or iodinated contrast agents.

Warnings

Two (2) anaphylactic deaths have been reported following ICG injection during cardiac catheterization. One of these was in a patient with a history of sensitivity to penicillin and sulfa drugs.

The Water for Injection provided for this product, pH 5.0 to 7.0, is specially prepared and should be used to dissolve ICG because there have been reports of incompatibility with some commercially available Water for Injection.

Each vial is intended for use in only one patient. Any prepared ICG solution remaining after each SPY *Elite*™ System imaging procedure must be discarded.

Precautions

Sterile techniques should be used in handling the ICG imaging agent solution.

Once reconstituted, the ICG imaging agent solution must only be used for one patient and within 6 hours.

ICG powder may cling to the vial or lump together prior to reconstitution because it is freeze-dried in the vials. *This is not due to the presence of water* – the moisture content is carefully controlled. The ICG is suitable for use.

The SPY *Elite*™ Kit and the outside of the vials are **NOT** sterile. The contents of the vials are sterile and must be handled aseptically to maintain the sterile field during surgery.

Radioactive iodine uptake studies should not be performed for at least a week following the use of ICG.

Pregnancy Category C: Animal Reproduction studies have not been conducted with ICG. It is not known whether ICG can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ICG should be given to a pregnant woman only if clearly indicated.

Nursing Mothers: It is not known whether this drug is

excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ICG is administered to a nursing woman.

Only use ICG at indicated doses and concentrations as defined in the SPY *Elite*™ Kit Instructions for Use or SPY *Elite*™ System Operator's Manual.

Do not use ICG vials that appear to have seals that are compromised in any way.

ICG is generally injected through a shared intravenous line with no reported difficulties or unexpected results to date. However, drug/drug interactions have not been studied.

Adverse Reactions

Anaphylactic or urticarial reactions have been reported in patients with or without history of allergy to iodides. If such reactions occur, immediate treatment with the appropriate agents, e.g., epinephrine, antihistamines, and corticosteroids should be administered. Resuscitative measures may also be required.

THE SPY ELITE™ STERILE DRAPE

Warning

The SPY *Elite*™ Sterile Drape is supplied sterile and is intended for single use only. **DO NOT RE-STERILIZE OR RE-USE.** If a drape becomes compromised during the protection of the imaging arm, or the imaging procedure, move the device away from the sterile field, remove the contaminated drape and replace with a new sterile drape, as per the instructions in this **Instructions for Use.**

Precautions

Use only SPY *Elite*™ Sterile Drapes.

The SPY *Elite*™ Kit and the packaging of the SPY *Elite*™ Sterile Drape are **NOT** sterile. The SPY *Elite*™ Sterile Drape is

supplied sterile and must be handled aseptically to maintain the sterile field during surgery.

Do not use drapes in which the seals on the package appear to be compromised in any way.

Instructions for Use

The Instructions for Use for the SPY *Elite*™ Kit is divided into two sections, one to detail the use and handling of the SPY *Elite*™ Sterile Drape with the SPY *Elite*™ System, the other for the handling, preparation and injection of ICG.

Applying the SPY *Elite*™ Sterile Drape

1. The non-sterile operator orients the mast (the proximal section of the arm) toward the sterile field, then extends the arm by pulling the Imaging Head away from the cart and rotates the Imaging Head so that the buttons are facing the floor.



2. The package containing the SPY *Elite*™ Sterile Drape is removed from the Kit. Using proper sterile technique, the package containing the sterile drape is opened and transferred to the sterile operator.



3. The sterile operator holds the sterile drape by placing both hands inside the folds of the sterile drape such that the exterior surface of the optical window is facing the floor.

4. The sterile operator drapes the Imaging Head and positions the optical window, so that it is approximately aligned with the flange on the Imaging Head. The non-sterile operator may assist by holding the Imaging Head stationary at or below chest-height. **ONLY THE STERILE OPERATOR MAY TOUCH THE EXTERIOR SURFACE OF THE DRAPE.**



5. As the sterile drape is passed over the Imaging Head, the non-sterile operator grasps the sterile drape by the interior surface and unravels the remainder of the drape over the yoke and arm. Care should be taken to ensure that the drape is not stretched so tightly that movement of the Imaging Head or arm is impaired. The sterile operator attaches the optical window to the Imaging Head by seating the rim of the window onto the flange of the Imaging Head.



6. The sterile operator verifies that all degrees of motion of the Imaging Head are available and not restricted by the sterile drape and that the optical window is securely seated on the Imaging Head.



7. The sterile operator fastens the ties around the yoke and arm to ensure that the sterile drape is attached securely. Note the location of the ties in the center of the yoke and arm sections. (Placing the tie closest to the Imaging Head above the yoke may restrict movement of the Imaging Head.)



If the SPY *Elite*™ Sterile Drape should become contaminated at any time during the procedure, it should be replaced with a new SPY *Elite*™ Sterile Drape and applied to the SPY *Elite*™ Device in the manner outlined above.

HANDLING, PREPARATION AND DOSAGE OF ICG

Supplies Required

Depending on the number of images being performed one (1) or two (2) vials of ICG and one (1) or two (2) vials of Water for Injection are required for each patient's imaging procedure.

For each imaging sequence, a set of the following supplies are required:

- One (1) 10ml syringe for reconstituting the ICG with the Water for Injection
- One (1) 3ml or 5ml syringe
- One (1) 10 ml syringe for the saline bolus
- Sterile normal saline for injection

Important notes :

- Use of a three-way stopcock is recommended to facilitate prompt administration of the saline flush following injection of the ICG into the infusion line.
- A dedicated line is not required for ICG injection.
- The ICG can be reconstituted and prepared for injection either at the beginning of, or during, the surgery, depending on the preference of the surgical team, but must be used within 6 hours of preparation.
- There are no known drug/drug interactions with ICG.

Dosage information

For *Plastic, Reconstructive and Micro-surgery applications* the recommended injection volume is 2 ml for most imaging sequences, except for images acquired through the patient's skin, in which case a 4 ml injection is recommended.

For *Gastrointestinal Surgery applications* the recommended injection volume is 2ml.

Prescribed dosages are at the medical discretion of the prescribing physician.

The total dose of ICG injected should be kept to below 2 mg/kg.

Preparation of ICG for Administration

- Draw up the entire 10 ml of Water for Injection into a 10 ml syringe.
- Remove the flip-off cap on the first ICG vial (25 mg) and inject the Water for Injection through the stopper into the ICG vial. This yields a 2.5 mg/ml solution of ICG. Shake the ICG vial gently to mix.
- Mix the contents of the ICG vial thoroughly and inspect the reconstituted vial for precipitation. If precipitation is noted, continue to gently shake until all ICG is dissolved into solution.

If precipitation persists, do **NOT** use the mixture. Discard the reconstituted vial and prepare a new vial, **as** described above.

In order to ensure that the reconstituted solution is used within 6 hours from the time of reconstitution, it is recommended that the second vial of ICG be reconstituted only once the first reconstituted solution has been used up.

Saline Flush Preparation

With an individual 10 ml syringe, withdraw 10 ml of normal saline.

Administration via a Central or Peripheral Venous Line

ICG administration is to be performed via a central or peripheral venous line. Using a three-way stopcock attached to an injection port on the infusion line, inject the prepared

2.5 mg/ml ICG solution into the central or peripheral line as a tight bolus. Immediately switch access on the stopcock to the syringe containing saline and briskly flush the ICG bolus through the line with 10 ml of sterile saline.

Optimal image quality is achieved when the injection of ICG enters the field of view as a sharp wave-front. This requires that dilution of the ICG solution be minimized prior to the bolus entering fast flowing blood (i.e. the central venous system). Attention to the following principles will help to optimize image quality:

- If the ICG is administered via a fluid infusion line, ensure that flow from the infusion bag is clamped off prior to injecting the ICG into the line.
- Ensure that the “dead space” between the site of injection of ICG and the entry point into the blood vessel is sufficient to accommodate the full volume of the ICG solution. Failure to do so may result in a partial volume of the bolus entering the blood vessel during injection of the ICG into the line and a smaller than anticipated volume being administered with the saline flush. This will effectively result in under-dosing for the image acquisition.
- Promptly push the bolus of ICG with a brisk flush of 10 ml sterile saline. This is particularly important when peripheral venous access is employed as this will minimize dilution in slow flowing blood, e.g. in the antecubital vein, prior to the bolus reaching fast flowing blood in the central circulation.

Timing of ICG Administration

ICG injection must only occur after the Imaging Head is positioned at the correct distance from the subject and motionless, and there has been coordinated communication between the operator of the SPY *Elite*™ Device and the anesthesiologist regarding route and timing of ICG injection.

The SPY *Elite*™ System supports acquisition buffering that captures images for a pre-defined period of time before the operator begins recording. This is provided to better ensure that the initial few seconds of fluorescence are captured.

Image buffering should be started before or simultaneously when the ICG is administered. With acquisition buffering enabled, recording should then be started at the first signs of ingress of ICG. For more details, please refer to the SPY *Elite*™ System Operator's Manual.

Discard any unused reconstituted ICG after the surgery is complete. Only use the instructions for ICG preparation and injection outlined in this **Instructions for Use** or in the SPY *Elite*™ System Operator's Manual.

HOW SUPPLIED

The SPY *Elite*™ Kit, the packaging of the SPY *Elite*™ Sterile Drape and the outside of the vials are **NOT** sterile. The SPY *Elite*™ Sterile Drape and the contents of the vials are supplied sterile and must be handled aseptically to maintain the sterile field during surgery.

The SPY *Elite*™ Sterile Drape and ICG are supplied for single patient use only. **DO NOT RE-STERILIZE. DO NOT RE-USE.**

Each vial of ICG should be reconstituted with an entire single 10 ml vial of Water for Injection just prior to the imaging procedure(s). Any prepared ICG solution remaining at the end of a procedure must be discarded.

STORAGE

The SPY *Elite*™ Pack should be stored at ambient room temperatures of 20° to 25°C (68° to 77°F).

TECHNICAL INFORMATION

For technical information or additional supplies, contact LifeCell™ Customer Solutions at 1-800-367-5737.

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