

IC-Green® (indocyanine green for injection)

Minimally Invasive Surgery (MIS) Focus



Diagnostic Green is the leading provider of trusted high quality fluorescence products, for physicians worldwide

Minimally Invasive Surgery (MIS), using small incisions to minimize trauma to normal tissues and adjacent organs, is now the preferred method of undertaking many surgeries. The global minimally invasive surgical systems market grew at a CAGR of 10.9% from 2020 to 2025, driven by the rapidly increasing demand from the patients undergoing minimally invasive surgical procedures, increasing surgical need, and the surge in the prevalence of colorectal and other gastrointestinal diseases.¹ New technological advancements, such as miniaturization of surgical equipment and development of surgical robots, have substantially increased the number of minimally invasive surgeries performed across the world.

USE OF ICG IN MINIMALLY INVASIVE SURGERIES INCLUDE:

Visualization of Structures	Vascular Assessment
Laparoscopic Cholecystectomy (Lap Chole)	Laparoscopic Colectomy Oesophagectomy

Laparoscopic Cholecystectomy (Lap Chole)

Laparoscopic Cholecystectomy is the gold standard for gallbladder surgery and is one of the most common surgeries undertaken worldwide. In the USA an estimated one million Lap Chole's are undertaken each year, with an estimated 500,000 in Europe.² Whilst the incidence of Bile Duct Injury (BDI) is low at 0.5%, due to the considerable amount of surgeries, this becomes quite a significant number with thousands of resultant patients per year thus sustaining BDI's, with severe and long term implications for their health.² The primary cause of error in 97% of Lap Chole cases was a visual perception illusion, which is one of the major drawbacks of an MIS approach.³

X-Ray Cholangiography has been used in the past to overcome this visualization problem. However it has drawbacks that are not apparent with Indocyanine Green (ICG) use.

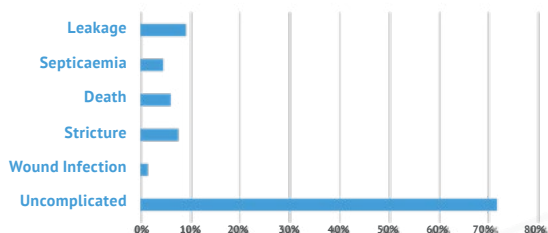
ICG Guided Cholecystectomy	X-Ray Cholangiography
Less expensive per patient vs. X-Ray cholangiography	Requires additional equipment and manpower
No radiation exposure	Involves radiation exposure
Non-invasive and less time consuming	Requires dissection of the cystic duct which takes procedure time
Highly specific (anatomy identified at a significantly higher rate) with minimal learning curve required	Interpretation relies on the expertise of the surgeon

Recently, a RCT demonstrated that ICG fluorescence cholangiography was equivalent to X-Ray cholangiography in its ability to visualize the critical junction (junction between the cystic duct, common hepatic duct and common bile duct).⁴ ICG fluorescence cholangiography was a faster procedure and has been shown to be a simple and cost-effective technique to recognize the biliary structures.^{4,5}

ICG fluorescence imaging during laparoscopic cholecystectomy (Lap Chole) surgery reduces BDI injuries and improves patient outcomes

THE BILE DUCT INJURY (BDI) RATE WITH LAPAROSCOPIC CHOLECYSTECTOMY IS REPORTED TO BE 0.5%², AND WHILE RELATIVELY LOW, WHEN INJURIES OCCUR, THEY CAN BE CATASTROPHIC.⁶

Outcome of Common Bile Duct Injuries following Cholecystectomy.⁴

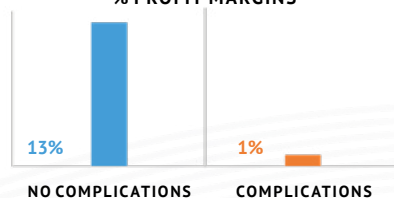


THE PRIMARY CAUSE OF ERROR IN 97% OF CASES WAS A VISUAL PERCEPTION ILLUSION.⁴



Surgeons had a 3-fold improvement in ability to visualize critical bile duct structures using ICG.⁷

LAP CHOLE HOSPITAL % PROFIT MARGINS



Profit margins at hospitals drop from 13% to 1% when complications in lap chole surgeries occur.⁸

Colorectal Surgery

Colorectal surgery frequently involves bowel resection with restoration of the alimentary tract by anastomosis. Indocyanine green (ICG) fluorescence imaging has proven to be an effective tool to assess anastomotic perfusion. Its use for the prevention of anastomotic leaks (AL) has been gaining popularity, with accumulating data on lower leak rates with (ICG) fluorescence guided surgery.^{9,12}

Most common methods used to evaluate the perfusion status of the colon has been to visually observe the change in color of the colon wall with the surgeon's naked eye and to carefully observe the pulse of the colon wall. However, these methods are subjective and not always accurate. Reported rates of anastomotic leakage vary from 3-6% in experienced colorectal surgeons and 3-25% overall.¹⁰ Combining the use of ICG with a near-infra red (NIR) laparoscopic camera system offers the surgeon the possibility of an objective, real-time assessment of blood flow to the colon.

COMPLICATIONS VARY BY PROCEDURE

Procedure	Leak Rate	Mortality
Colon Resection	2.7%	Up to 15%
Rectal Resection	5-20%	Up to 10%
Oesophagectomy	4-25%	Up to 50%
Total/Partial Gastrectomy	5-12%	Up to 20%
Sleeve Gastrectomy	1-4%	Up to 5%



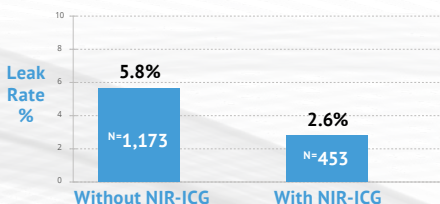
ICG PROVEN TO REDUCE LEAK RATES IN COLORECTAL SURGERY

There is a growing body of evidence that proves the significant value of using ICG in colorectal surgery. Below is a summary of two recent Clinical Trials proving that ICG is safe, effective and is increasingly viewed as the gold standard in laparoscopic colorectal procedures.

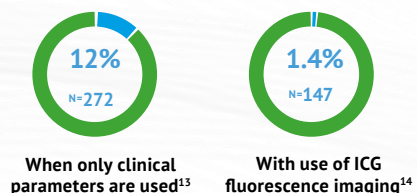
Study	Results	Study Conclusions
Multicenter phase II trial of near-infra red imaging in elective colorectal surgery. ¹¹	NIR ICG assessment change in site of bowel division 29 patients (5.8%) no subsequent leak rates in these patients. Overall Leak Rate Standard White light 5.8% versus NIR ICG 2.6% . Left Anterior Resections Standard White light 10.7% versus NIR ICG 3% .	NIR-ICG use may change intraoperative decisions, which may lead to a reduction in anastomotic leak.
Blood perfusion assessment by indocyanine green fluorescence imaging for minimally invasive rectal cancer surgery (EssentiAL trial): A randomized clinical trial. ¹²	The rate of anastomotic leakage (Grade A+B+C) was significantly lower in the ICG+ group (7.6%) than in the non-ICG group (11.8%) . The rate of anastomotic leakage (Grade B+C) was 4.7% in the ICG+ group and 8.2% in the non-ICG group .	839 patient study which showed that ICG-cohort saw that ICG-fluorescence significantly reduced the anastomotic leakage rate by 4.2% .

ICG fluorescence imaging during colorectal surgery reduces the rate of leaks experienced by patients

OVERALL LEAK RATE IN PATIENTS UNDERGOING COLORECTAL SURGERY¹¹



PATIENTS EXPERIENCING ANASTOMOTIC LEAKS FOLLOWING COLORECTAL RESECTION SURGERY



Mortality rates associated with anastomotic leaks, range from 5-17%.¹⁵
 Profit margins at hospitals drop by 8% when complications in colon surgeries occur.⁸

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IC-GREEN® (INDOCYANINE GREEN FOR INJECTION), FOR INTRAVENOUS OR INTERSTITIAL USE - PRESCRIBING INFORMATION

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use IC-Green® (indocyanine green for injection) for intravenous or interstitial use safely and effectively. See full prescribing information for IC-Green® (indocyanine green for injection), for intravenous or interstitial use.

INDICATIONS AND USAGE

IC-Green® (indocyanine green for injection) is a tricarbocyanine dye, is indicated for:

- Fluorescence imaging of vessels (micro- and macro-vasculature), blood flow and tissue perfusion before, during and after vascular, gastrointestinal, organ transplant, plastic, micro- and reconstructive surgeries, including general minimally invasive surgical procedures, in adults and pediatric patients aged 1 month and older
- Fluorescence imaging of extrahepatic biliary ducts in adults and pediatric patients aged 12 years and older
- Fluorescence imaging of lymph nodes and lymphatic vessels during lymphatic mapping in adults with cervical and uterine cancer
- Ophthalmic angiography in adults and pediatric patients

DOSAGE AND ADMINISTRATION

Indicator-Dilution Studies.

Under sterile conditions, the IC-Green® (indocyanine green for injection) powder

should be dissolved with the Sterile Water for Injection, USP provided and the solution used within 6 hours after it is prepared. The usual doses of IC-Green® (indocyanine green for injection) for dilution curves are: Adults 5.0 mg, Children - 2.5 mg, and Infants - 1.25 mg.

Hepatic Function Studies.

Under sterile conditions, the IC-Green® (indocyanine green for injection) powder should be dissolved with the Sterile Water for Injection, USP provided. The patient should be weighed and the dosage calculated on the basis of 0.5 mg/kg of body weight. Exactly 5 mL of Sterile Water for Injection, USP should be added to the 25 mg vial giving 5 mg of dye per mL of solution.

Ophthalmic Angiography Studies.

Dosages up to 40 mg IC-Green® (indocyanine green for injection) dye in 2 mL of Sterile Water for Injection, USP should be administered. A 5 mL bolus of normal saline should immediately follow the injection of the dye.

DOSAGE FORMS AND STRENGTHS

IC-Green® (indocyanine green for injection) Injection is a sterile, lyophilized green powder containing 25 mg of indocyanine green with no more than 5% sodium iodide.

CONTRAINDICATIONS

IC-Green® (indocyanine green for injection) Injection contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides because of the risk of anaphylaxis.

WARNINGS AND PRECAUTIONS

- Hypersensitivity reactions including anaphylaxis and urticaria have occurred. Always have cardiopulmonary resuscitation personnel and equipment readily available to monitor patients.
- IC-Green® (indocyanine green for injection) is unstable in aqueous solution and must be used within 6 hours
- Radioactive iodine uptake studies should not be performed for at least a week following the use of IC-Green® (indocyanine green for injection).

ADVERSE REACTIONS

Most common adverse reactions are anaphylactic or urticarial reactions. These have been reported in patients with and without a history of allergy to iodides.

To report SUSPECTED ADVERSE REACTIONS, contact Diagnostic Green LLC at 1-844- 424-3784 (1-844-ICG-DRUG) or e-mail: drugsafety@diagnosticgreen.com; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Products containing sodium bisulfite reduce the absorption peak of IC-Green® (indocyanine green for injection) in blood.

For full prescribing information go to www.diagnosticgreen.com

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