


# Synergy<sup>ID</sup>™ System Scientific Update

Main peer-reviewed journal articles that describe the clinical benefits of NIR/ICG imaging



The Synergy<sup>ID</sup> endoscopic imaging system is indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. Upon intravenous administration and use of ICG consistent with its approved label, the system enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visualization of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (eg, cystic duct, common bile duct, or common hepatic duct), using near-infrared imaging.

Fluorescence imaging of biliary ducts with the Synergy<sup>ID</sup> system is intended for use with standard-of-care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Upon interstitial administration and use of ICG consistent with its approved label, the Synergy<sup>ID</sup> Endoscopic Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Please note that the indications for use above are applicable for the United States. For the European Union mark, the indications are as follows: The Synergy<sup>ID</sup> endoscopic imaging system is indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging.

## Colorectal Surgery

[Multicentre phase II trial of near-infrared imaging in elective colorectal surgery.](#) *Br J Surg.* 2018;105(10):1359-1367. doi:10.1002/bjs.10844

- Anastomotic leaks (AL) are one of the most feared complications in colorectal surgery owing to the associated clinical and economic consequences.
- Compromised perfusion (blood flow) at the anastomotic site is one of the main causes of AL, which can lead to necrosis.

### Takeaway

This multicenter Phase II trial consisting of 504 patients concluded that NIR/ICG perfusion assessment reduced the overall anastomotic leak rate from 5.8% to 2.6% ( $P = .009$ ). This represents a 55% reduction in leaks, calculated as  $(5.8-2.6)/5.8$ .

Ris F,  
Liot E,  
Buchs NC,  
Kraus R,  
Ismael G,  
Belfontali V,  
Douissard J,  
Cunningham C,  
Lindsey I,  
Guy R,  
Jones O,  
George B,  
Morel P,  
Mortensen NJ,  
Hompes R,  
Cahill RA,



Way LW,  
Stewart L,  
Ganert W,  
Liu K,  
Lee CM,  
Whang K,  
Hunter JG

Dip F,  
LoMenzo E,  
Sarotto L,  
Phillips E,  
Todeschini H,  
Nahmod M,  
Alle L,  
Schneider S,  
Kaja L,  
Boni L,  
Ferraina P,  
Carus T,  
Kokudo N,  
Ishizawa T,  
Walsh M,  
Simpfendorfer C,  
Mayank R,  
White K,  
Rosenthal RJ

## Laparoscopic Cholecystectomy

[Causes and prevention of laparoscopic bile duct injuries: analysis of 252 cases from a human factors and cognitive psychology perspective.](#) *Ann Surg.* 2003;237(4):460-469. doi:10.1097/01.SLA.0000060680.92690.E9

- Bile duct injuries (BDI) are serious, life-threatening, life-altering complications for laparoscopic cholecystectomy, the most common general surgery procedure.
- This study aimed to determine the cause of laparoscopic bile duct injuries.

### Takeaway

This retrospective study of the cause of bile duct injuries in 252 cases determined that 97% were caused by misidentification of the biliary anatomy. Surgeons believed they were clipping/cutting the cystic duct, when in fact they were dealing with a different duct.

[Randomized trial of near-infrared incisionless fluorescent cholangiography.](#) *Ann Surg.* 2019;270(6):992-999. doi:10.1097/SLA.0000000000003178

- This multicenter clinical trial included 8 institutions, 5 countries, and 639 patients.
- A single-blind, randomized, 2-arm trial compared the efficacy of NIR/ICG imaging and white light alone.
- The detection rate of 7 biliary structures—the cystic duct, right hepatic duct, common hepatic duct, common bile duct, cystic common bile duct junction, cystic gallbladder junction, and accessory ducts—was evaluated.

### Takeaway

NIR/ICG imaging provides 3 times better visualization of extrahepatic biliary structures when compared to white light alone.

### Collective Takeaway

Since bile duct injuries are fairly rare (0.5% to 1% occurrence), to statistically power a study to prove NIR/ICG imaging reduces injuries would require nearly 25,000 patients, which is clearly not feasible. These 2 studies are important because if we know why bile duct injuries occur (97% due to misidentification of the anatomy) and that NIR/ICG imaging improves identification of the anatomy by a factor of 3 times, we can confidently infer that using this technology will reduce bile duct injuries.