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System Overview

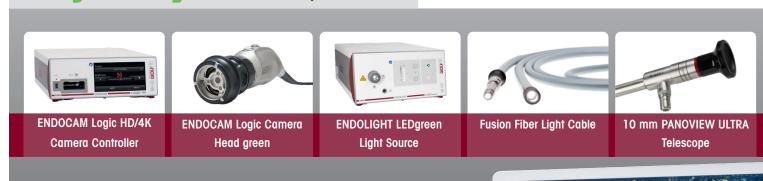
The newest member of the ENDOCAM® Logic family, **System green**, enables simultaneous real-time ICG/NIR fluorescence and standard white light imaging with the ENDOCAM® Logic HD and 4K camera platforms, making it ideal for both new and existing customers as it expands the application and visualization capabilities of Richard Wolf's OR platform.

Clinical Indications

System green enables ICG/NIR fluorescence imaging which has become a valuable technology in the field of minimally invasive surgery for different procedural applications like:

- Intraoperative assessment of visceral perfusion
- Visualization of biliary structures in fluorescence cholangiography
- Visualization of the lymphatic system, including lymphatic vessels and lymph nodes

System green Components







System green Fluorescence Modes

Mode	Advantage	Example Image		
Standard White Light Endoscopy Mode	High definition standard white light endoscopic image			
greenICG Fluorescence Mode white light visualization combined with the green overlay ICG/NIR fluorescence image information	Allows the tissue to be differentiated with a high level of detail and contrast	פייתוב		
greenICG pure Fluorescence Mode grayscale visualization (to boost contrast) combined with the green overlay ICG/NIR fluorescence image information	 Enables specific, high-contrast visualization as well as differentiation of tissue structures Detailed examination of key structures is possible (e.g., mapping and identification of lymph nodes and lymphatic channel drainage) 			

One fluorescence mode, greenICG or greenICG pure, can be selected at a time via the touch screen on the ENDOCAM Logic camera controller. The end user can then switch between the chosen mode and standard white light endoscopy mode using one of the following:

- Camera Head Button
- ENDOLIGHT LEDgreen Light Source
- Footswitch (optional accessory)
- USB Keyboard (optional accessory)





System green Capabilities

For quick and easy switching of modes intraoperatively, the "Changing the Mode" function enables the System green

Special Imaging Modes to be cycled through utilizing a camera head button.



With System green, the fluorescent image can also be displayed in six different colors:

- Green
- Blue
- Cyan
- Red
- Magenta
- Yellow







Tissue Perfusion Visualization

Example Procedure: Colorectal Resection

Why Use ICG?

Restoring normal function and tissue healing after surgical intervention is, among others, critically dependent on tissue perfusion. Insufficient perfusion with oxygenated blood could result in ischemia and subsequent tissue damage. A significant clinical problem is anastomotic leakage, which is one of the most serious complications after gastrointestinal surgery.

Clinical Advantages

- Provides surgeons with the ability to visualize visceral perfusion, allowing for optimal transection during colon resection
- Significantly decreases occurrence of anastomotic leakage during colorectal surgery²



Colon Surgery Using Fluorescence Guided Surgery Explained





Perfusion evaluation of a colorectal anastomoses

Dosing Parameters

Procedure	Purpose	Injection Type	Usual Dosage	Injection Time	First ICG Detection	ICG Duration	Notes
Colorectal Resection	Tissue Perfusion Visualization	Intravenous	3-3.5 mL + 10 cc saline flush	Intraoperatively	30-60 seconds post-injection	Arterial & Venous phase, min	Evaluate resection margin

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DISCLAIMERS

- The above dosage and timing information have been collated from worldwide surgeon experts in these procedures and is based on their recommendations and is not evidence-based.
- All dosages have been adjusted to the U.S. recommended dilution of 25mg of ICG in 10mL of sterile water
- Doses are device-dependent.
- Approval for listed indications may vary according to country.
- Indocyanine Green for Injection USP 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.
- For any further questions on dosing, please contact ISFGS at admin@isfgs.org
- Only pharmaceuticals specially certified for this use and applied in accordance with the manufacturer's specifications may be used as an indicator substance for fluorescence (e.g., indocyanine green (ICG)).

 Richard Wolf does not assume any responsibility for the administration or effect of the indicator substances.

^{1.} van Manen, L., Handgraaf, H. J., Diana, M., Dijkstra, J., Ishizawa, T., Vahrmeijer, A. L., & Mieog, J. S. D. (2018). A practical guide for the use of indocyanine green and methylene blue in fluorescence guided abdominal surgery. Journal of surgical oncology, 118(2), 283-300.

^{2.} Safiejko K, Tarkowski R, Kozlowski TP, Koselak M, Jachimiuk M, Tarasik A, Pruc M, Smereka J, Szarpak L. Safety and Efficacy of Indocyanine Green in Colorectal Cancer Surgery: A Systematic Review and Meta-Analysis of 11,047 Patients. Cancers. 2022; 14(4):1036.

Bile Duct Visualization





Why Use ICG?

Bile duct injury is one of the most serious complications that may occur during laparoscopic cholecystectomy.

Intraoperative misidentification of biliary anatomy is often the main cause of bile duct injury.³ The use of real-time ICG

fluorescence may significantly improve the visualization and identification of the extrahepatic biliary tree, therefore reducing the risk of bile duct injury.

Clinical Advantages

- Improved visualization of relevant anatomy leading to:
 - 4x reduced risk of common bile duct injury⁴
 - 16x reduced incidence of conversion to open procedure⁴







Gallbladder Removal Using Fluorescence Guided Surgery Explained



Guided Imaging in Laparoscopic.



Live Surgery: Fluorescent Insicionless Cholangiography with ICG

Dosing Parameters

Procedure	Purpose	Injection Type	Usual Dosage	Injection Time	First ICG Detection	ICG Duration	Notes
Cholecystectomy	Bile duct visualization	Intravenous	0.4 mL-2.5 mL, equipment-de- pendent	Recommended: At least 45 min before procedure	After Calot triangle is exposed	Visible during surgery	Reflux maneuver visualize cystic duct

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- 4. Dip F, Lo Menzo E, White KP, Rosenthal RJ. Does near-infrared fluorescent cholangiography with indocyanine green reduce bile duct injuries and conversions to open surgery during laparoscopic or robotic cholecystectomy? - A meta-analysis. Surgery. 2021 Apr;169(4):859-867. doi: 10.1016/j.surg.2020.12.008. Epub 2021 Jan 18. PMID: 33478756.

Lymphatic System Visualization





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Why Use ICG?

Studies suggest that sentinel lymph node (SLN) mapping is an "accurate and feasible method"⁵ for the assessment of lymph nodal involvement in cervical/endometrial cancer. The use of ICG fluorescence for SLN mapping has shown optimized sensitivity and significantly increased detection rates compared to SLN with other modalities.⁶ The improvement in detection rates may lead to the need for fewer complete lymphadenectomies for patients and therefore, reduced surgical times and complications associated with lymphadenectomies.⁵

Clinical Advantages

- Improved visualization of relevant anatomy leading to:
 - Improved detection rates of SLN over other modalities⁶
 - Improved bilateral optimal mapping in women with early stage endometrial and cervical cancer over the standard technetium-99m radiocolloid with blue dye⁶



Dosing Parameters

Procedure	Purpose	Injection Type	Usual Dosage	Injection Time	First ICG Detection	ICG Duration	Notes
Cervical/ Endometrial Cancer	Visualization of lymphatic drainage & SLN	Cervical submucosa and deep into stroma (1 cc each)	1 mL at quadrants 3 and 9 (2.5 mg/mL)	Prior to dissection & insertion of uterine manipulator	At start of procedure	Stable during surgery; Slowly diffuses through lymphatics;	Total 4 cc

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2298-06.01-1223USA

Lymphatic System Visualization

Example Procedure: Colorectal & Gastrointestinal Carcinoma



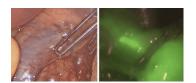
Why Use ICG?

Studies suggest that ICG fluorescence-guided laparoscopic lymphadenectomy is safe and effective in prolonging survival among patients with resectable Gastric Cancer when compared to conventional lymphadenectomy. ICG fluorescence aids in the identification of lymph nodes and therefore helps increase the number of lymph nodes retrieved during a procedure.

This, in turn, has shown improvement in the three-year overall survival and disease-free survival rates as well as in recurrence patterns.

Clinical Advantages

- Improved visualization of relevant anatomy leading to:
 - Improved identification of lymph nodes and tracts during dissection
 - Increased number of lymph nodes retrieved in laparoscopic gastrectomy for gastric cancer⁷



Sentinel lymph node with white light and with fluorescence



Sentinel Lymph Node Mapping Using Near



Lymph Node Mapping in Colorectal Cancer Surgery with Dr. Gabriel La



Dosing Parameters

Procedure	Purpose	Injection Type	Usual Dosage	Injection Time	First ICG Detection	ICG Duration	Notes
Colorectal & Gastrointestinal Carcinoma	Visualization of lymphatic drainage & SLN	Peritumoral area	0.5-1 mL on each tumor quadrant	Preoperatively or intraoperatively	Abdominal cavity visualized	Remains stable during surgery; Slowly diffuses through lymphatics;	Esophageal LN mapping: create & inject into bleb to prevent too deep injection; Gastric LN mapping during gastrectomy: peritumoral injection 24 hrs prior for lymphadenectomy; intraoperative injection for SLN mapping;

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