



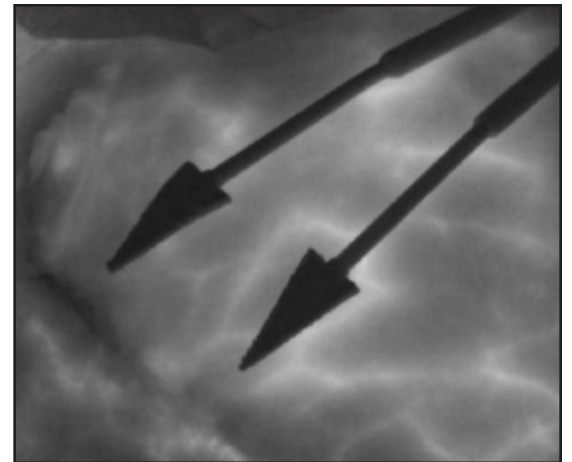
SPY IMAGING SYSTEM PROVIDES REAL-TIME IMAGES ALLOWING SURGEONS TO REVIEW OPERATIVE PLANS AND OPTIMIZE OUTCOMES

The first clinical experience utilizing laser-assisted, indocyanine green fluorescent-dye angiography (LA-ICGA, specifically using the SPY Imaging System manufactured by Novadaq Technologies) for breast reconstructive surgery was presented in June, 2007 at the World Congress for Reconstructive Micro Surgery, held in Athens, Greece.

The study, presented by Michel C. Samson, MD,¹ interim Chairman, Department of Plastic Surgery at Cleveland Clinic in Florida, confirmed that the use of intra-operative real-time, laser-assisted fluorescent imaging during free-flap breast reconstructive surgery may result in improved intra-operative decision making for surgeons performing complex plastic surgery procedures and ultimately positively impact procedural outcomes for patients.

“Free tissue transfer is the most advanced and technically demanding form of reconstructive plastic surgery. This technique is utilized when reconstructing large defects created by trauma or neoplasm,” said Samson.

“Adequate blood-flow, both to and from transferred tissue, is the most critical component of this surgery. The ability to visually assess arterial inflow and venous return, on a real-time basis, during these complex procedures assists us with intra-operative decision making and may ultimately prove to impact outcomes,” according to study co-author Martin Newman, MD,¹ also of Cleveland Clinic in Florida.”



LA-ICGA in perforator flap surgery—perfusion following inset.

Laser-assisted, Intra-operative Imaging

LA-ICGA enables physicians to create real-time images of microscopic vessels intra-operatively—in minutes. This translates to significant advances in the art and science of plastic, micro- and reconstructive surgeries. Also of note is the ability to potentially reduce post-operative complications and therefore possibly reduce some of the psychological trauma associated with breast reconstruction surgery.

With LA-ICGA surgeons can:

- Pre-operatively visualize blood flow as an adjunct for the evaluation of circulation in the tissue.
- Intra-operatively assess blood flow in vessels and co-joined vessels.
- Post-operatively continue to adjunctively evaluate blood perfusion to the tissue.

DIEP Flap Using LA-ICGA

LA-ICGA performed using the SPY Imaging System offers an alternative interactive surgical tool for performing imaging during a variety of plastic and reconstructive surgeries including Deep Inferior Epigastric Perforator (DIEP) flap procedures. At the World Congress for Reconstructive Microsurgery, Samson and Newman presented their experience performing LA-ICGA during the harvest of the flap and following microsurgical anastomosis.

“Prior to harvest LA-ICGA imaging confirmed arterial inflow, venous return and flap perfusion through the entire sub-dermal plexus when intact. Following anastomosis and inset, LA-ICGA confirmed patency of the arterial and venous anastomoses, unobstructed flow throughout the pedicle, and perfusion of the subdermal plexus equal to that of the adjacent tissue,” wrote Newman and Samson in the Congress abstract.²


FDA Clearance Received

In January 2007, the US Food and Drug Administration (FDA) granted Novadaq's SPY Imaging System pre-market 510(k) clearance for use during plastic, micro- and reconstructive surgery.

This 510(k) premarket clearance means that the FDA deems the device to be substantially equivalent to a legally marketed device, which in this case is x-ray angiography.

The SPY Imaging System:

- Generates high-quality images, allowing surgeons to view valuable information in real-time during the course of surgery.
- Has shown great promise and given physicians additional confidence when performing autologous reconstruction surgeries.
- Is easy to use, does not involve ionizing radiation, compared with radiologic modalities, is less invasive and potentially less harmful to patients and staff.

SPY also received FDA 510 (k) clearance for use in coronary artery bypass surgery in January 2005. 

Novadaq Technologies provides intra-operative imaging systems, that may enable surgeons to:

- *Perform a variety of complex and demanding procedures.*
- *See what they've never seen before in-real time and while in the operating room.*
- *Leverage imaging to guide operative plans.*
- *Obtain real-time confirmation of the result of treatment.*

References:

1. Michel C. Samson, MD and Martin Newman, MD, currently serve as consultants for Novadaq Technologies.
2. Samson MC and Newman MI. Poster: Assisted Indocyanine Green Fluorescent-Dye Angiography in Perforator Flap Surgery. Presented at the VI Congress of the World Society for Reconstructive Microsurgery, Athens, Greece, June 2007.

To Learn More

To learn more about SPY and other Novadaq products, call 1-800-230-3352 (select option #2); email to CustomerService@novadaq.com; or visit the company's Web site at www.novadaq.com.