

For Patients and General Audience

What is LumiSystem™?

LumiSystem is the combination of the following FDA approved products – LUMISIGHT™, an optical imaging agent, and Lumicell™ DVS, a fluorescence imaging device. These products are used as an adjunct by surgeons to intraoperatively detect residual breast cancer, in real-time, during lumpectomy surgery.

What is LUMISIGHT (pegulicianine)?

LUMISIGHT (pegulicianine) is an optical fluorescence imaging agent used in adults with breast cancer to help detect any remaining cancerous tissue at the surgical site following removal of the primary specimen during a lumpectomy procedure.

What is the Lumicell™ DVS?

The Lumicell™ Direct Visualization System (DVS) is for use in adults with breast cancer to help detect any remaining cancerous tissue at the surgical site following removal of the primary specimen during a lumpectomy procedure. The Lumicell DVS is used with LUMISIGHT™ (pegulicianine), an imaging agent to visualize the lumpectomy cavity

Indications for Use

LUMISIGHT, an optical imaging agent, and Lumicell DVS, a fluorescence imaging device, are indicated for fluorescence imaging in adults with breast cancer as an adjunct for the intraoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about LUMISIGHT?

LUMISIGHT may cause serious hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred in 4/726 (0.6%) of patients in clinical studies. Tell your doctor if you have any history of hypersensitivity reactions to pegulicianine or to contrast media or products containing polyethylene glycol (PEG).

Your healthcare provider should have emergency resuscitation drugs, equipment, and trained personnel available during use of LUMISIGHT. Healthcare providers should monitor all patients for hypersensitivity reactions and if one is suspected, immediately discontinue the injection and initiate appropriate therapy.

What other safety information should I know about LUMISIGHT?

- **Risk of Misdiagnosis:** The absence of a signal in surgery does not rule out cancer. Additionally, a positive signal may be seen in non-cancerous tissue.

- **Interference from Dyes Used for Sentinel Lymph Node Mapping:** Your healthcare provider should avoid using dyes before imaging with LUMISIGHT.

What are the most common side effects of LUMISIGHT?

The most common side effects ($\geq 1\%$) include hypersensitivity and an abnormal color in urine.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [MedWatch](#) or call 1-800-FDA-1088. Please see full [Prescribing Information](#), including Boxed Warning.

What is the most important information I should know about Lumicell DVS?

- **Adjunctive use:** Lumicell DVS is for use as part of the lumpectomy procedure and is not a replacement for the standard of care procedures and pathology. Your healthcare provider must be trained on proper use of the Lumicell DVS, and breast conserving surgery prior to performing any procedures.
- **Risk of Misdiagnosis:** The absence of a signal in surgery does not rule out cancer. Additionally, a positive signal may be seen in non-cancerous tissue.
- **Interference from Dyes Used for Sentinel Lymph Node Mapping:** Your healthcare provider should avoid use of dyes before imaging the lumpectomy cavity who have received LUMISIGHT.
- **Tissue perforation or damage:** During the procedure, your healthcare provider should avoid excessive pressure or torque with the handheld probe while inside the cavity as it can cause tissue perforation or damage.
- **Infection risk:** To avoid infection risk, the reusable handheld probe and cables should be properly and completely disinfected and reprocessed after each use by your healthcare provider. Your healthcare provider should also ensure proper use of the sterile, single-use probe cover.
- **Eye discomfort:** Your healthcare provider should avoid direct eye exposure to handheld light probe as it may cause pain.

Please see the LUMISIGHT [Prescribing Information](#), including Boxed Warning, and Lumicell DVS [Instructions for Use](#). For complete product information visit www.LumiSystem.com.