

 **LUMISYSTEM™**

**See what matters most.
Illuminate breast cancer in real-time.**




LUMICELL®

Important Safety Information

What is LUMISIGHT™ (pegulicianine) and Lumicell DVS?

- LUMISIGHT (pegulicianine) is an optical imaging agent and Lumicell DVS is a fluorescence imaging device. LUMISIGHT and Lumicell DVS, in combination, are 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 most important information to know about LUMISIGHT?

- **Hypersensitivity Reactions:** 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 the 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.
- The most common side effects ($\geq 1\%$) include hypersensitivity and an abnormal color in urine.

What additional important information should I know about LUMISIGHT and 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 lumpectomy procedure and pathology.
- **Risk of Misdiagnosis:** The absence of a signal in surgery does not rule out cancer. Additionally, a positive signal may be seen in noncancerous tissue.
- **Interference from Dyes Used for Sentinel Lymph Node Mapping:** Your healthcare provider should avoid use of dyes before imaging the lumpectomy cavity in patients who have received LUMISIGHT.
- **Other Risks:** Using the Lumicell DVS handheld probe may cause tissue damage or infection.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088. Please see the LUMISIGHT Prescribing Information, including Boxed Warning, and Lumicell DVS Instructions for Use. For complete product information www.LumiSystem.com.

Rx only

Introducing: LumiSystem

LumiSystem helps surgeons look inside the breast during surgery to check for cancer that might have been missed — giving them a better chance to remove it all the first time.



✓ **84%**

Clinical trial results showed that LumiSystem correctly identified when cancer was present (true positive) and when cancer was not there (true negative) with an accuracy of 84%.¹

"Just knowing that my doctor took the time to take a second look for residual cancer during my surgery brought me great peace of mind, and I would recommend it highly."

- Nancy
Actual Patient

**Ask your doctor if
LumiSystem is right for you.**

LUMICELL™ DVS
DIRECT VISUALIZATION SYSTEM



LUMISIGHT™
(pegylolamine) for injection



How LumiSystem Works: Lighting Up Cancer to Help Surgeons See More Clearly

Before surgery, patients are given a special imaging agent called LUMISIGHT (pegulicianine) through a simple injection. On its own, LUMISIGHT is like a light switch that's turned off — it doesn't glow yet.

But here's where it gets smart:

Cancer cells and some nearby immune cells release special enzymes that help the tumor grow and spread. LUMISIGHT is designed to detect those enzymes. When LUMISIGHT comes into contact with them, it "switches on" — lighting up the suspicious tissue with a special fluorescent signal (a kind of light) that the surgeon can see only when using the LumiSystem camera during surgery.

This glowing effect helps the surgeon spot cancerous tissue more clearly in real time — making it easier to remove what's needed and potentially reduce the chance of needing a second surgery.



IV Injection

The patient receives an intravenous (IV) injection of LUMISIGHT (pegulicanine) about 2-6 hours before the surgery.



Standard Lumpectomy

(also known as partial mastectomy)

The surgeon performs the standard of care lumpectomy to remove the cancer.



Second Look with LumiSystem

After the primary tumor is removed, the surgeon uses the LumiSystem probe to scan inside the breast in search of cancer that may have been missed.

If the probe detects suspicious tissue the surgeon is alerted by a red signal that appears on an external monitor. The surgeon may decide to remove the suspicious tissue prior to completing the surgery.



Pathology Assessment

Once the suspicious tissue is removed, the surgeon completes the procedure and all removed tissues are sent to pathology for assessment.

For answers to
frequently asked
questions:



Prescribing Information Affixed Here

Reference

¹ Smith et al., NEJM Evidence 2, no. 7 (June 27, 2023). <https://doi.org/10.1056/EVIDoa2200333>.

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Manufactured for:
Lumicell, Inc.
307 Waverley Oaks Road
Suite 309
Waltham, MA 02452
617-404-1001

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