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## BACKGROUND

- Tumor-free margins are critical for local control in breast conserving surgery
- 20-40% of lumpectomy patients have positive margins that require surgical re-excision
- Tools are needed to identify residual tumor in patients at initial surgery
- The LUM Imaging System consists of intravenously injected LUM015 (protease-activated, fluorescence imaging agent), a hand-held wide field detector device and a decision software (proprietary algorithm)
- The LUM Imaging System is used to scan the surgical cavity walls intraoperatively after the resection of the main lumpectomy specimen

## STUDY DESIGN

- Non-randomized, prospective, multi-center feasibility study to train multiple sites on the proper use of the LUM Imaging System prior to the start of a pivotal study which will evaluate the safety and efficacy of the LUM Imaging System in reducing the positive margin rate in excised tissue during standard of care lumpectomies

## OBJECTIVES

- Train clinical staff and surgeons on integrating the LUM imaging system into surgical practice
- Compare fluorescent intensity between *in-vivo* and *ex-vivo* images
- Establish site-specific workflow for labeling shaves by orientation
- Correlate LUM System saved images with histopathology results
- Collect safety and efficacy data

## METHODS

Figure 1: LUM Imaging System in use

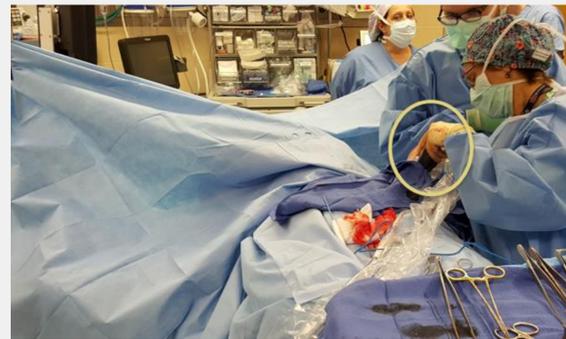


Figure 2: LUM optical head with sterile barrier



- Adult female breast cancer patients undergoing lumpectomies are being enrolled at community based and academic medical centers across the US
- Subjects are injected with LUM015 prior to surgery
- Surgeons perform standard of care lumpectomy
- LUM Imaging System is used intraoperatively and margins compared with pathology
- Shaves are obtained based on the LUM Imaging System
- Images of *in-vivo* tissue and *ex-vivo* tissue are recorded to measure the ratio of fluorescent intensity to verify that consistent tissue contact is made during lumpectomy cavity scanning
- Protocol-specific tools are used to maintain specimen orientation and naming to support study data integrity

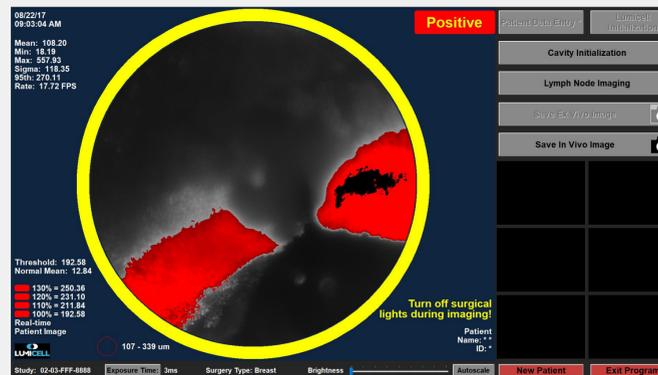


Figure 3: Visual display of the LUM Imaging System indicating potential residual cancer tissue in the lumpectomy tumor bed



Figure 4: Study tool to support data integrity by organizing shaves by orientation

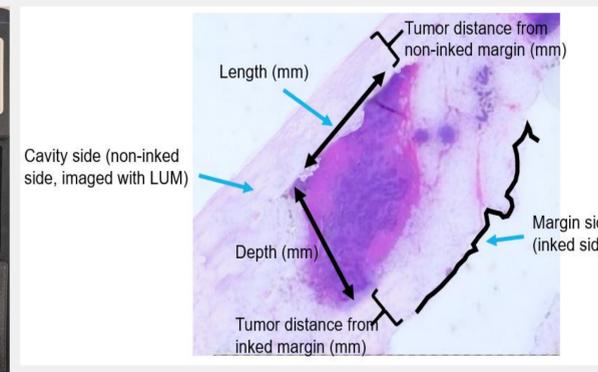


Figure 5: Study-specific pathology assessment of LUM guided shaves

## DISCUSSION

- LUM Imaging System training is intended to improve the quality and integrity of the data collected in the upcoming Pivotal clinical trial to evaluate the safety and efficacy of the LUM Imaging System. This System is also currently being evaluated in other cancer indications including gastrointestinal cancers, prostate cancer and brain cancer.

## ACKNOWLEDGEMENT

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