

# Diagnostic Accuracy of Point-of-Care Fluorescence Imaging for the Detection of Bacterial Burden in Wounds: Results from the 350-Patient FLAAG\* Trial

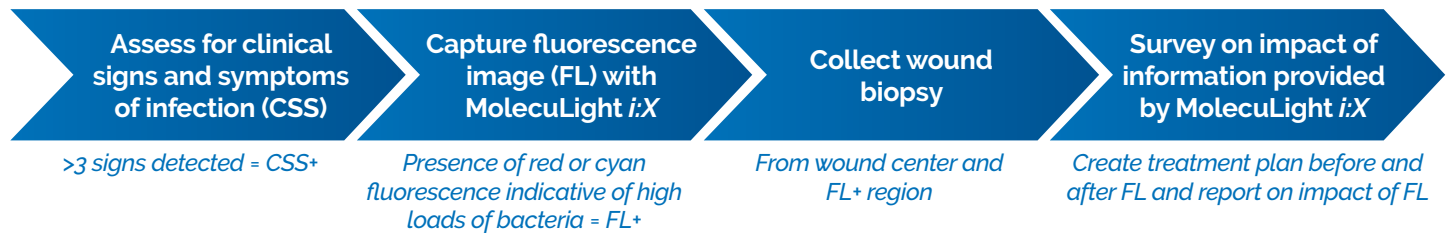
Le et al, Adv in Wound Care, 2020

## Clinical Trial Objectives

This prospective multi-center cross sectional Fluorescence imaging Assessment And Guidance (FLAAG) clinical trial evaluated:

1. Whether use of MolecuLight *i:X* in combination with clinical signs and symptoms (CSS) improves detection of high loads of bacteria ( $>10^4$  CFU/g) in wounds.
2. How information provided by MolecuLight *i:X* impacts treatment planning and patient care.

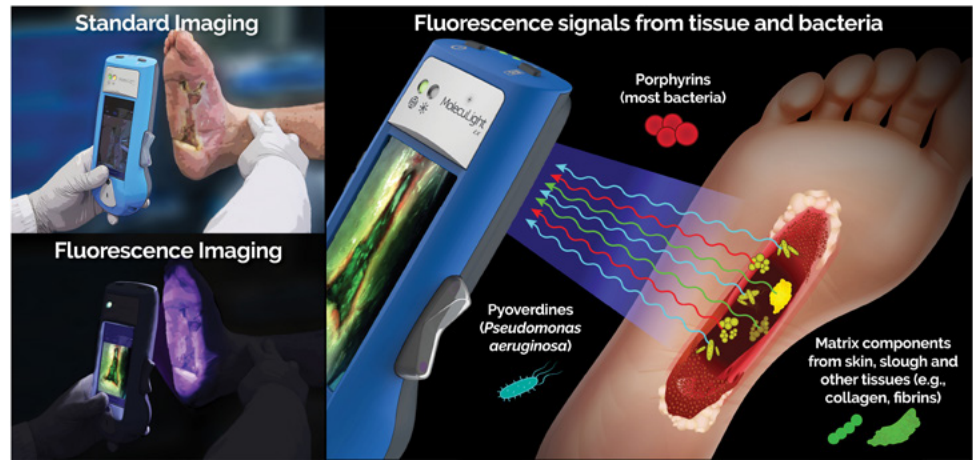
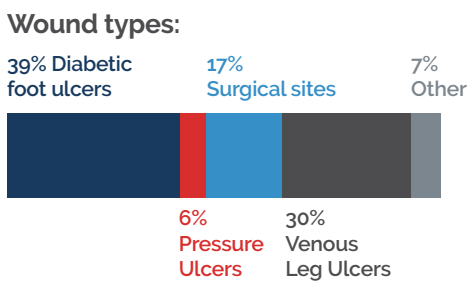
## Methods



### MolecuLight Fluorescence Imaging Procedure

The prospective, controlled clinical trial included:

- 14 U.S. clinical sites
- 20 clinicians
- 350 chronic wound patients

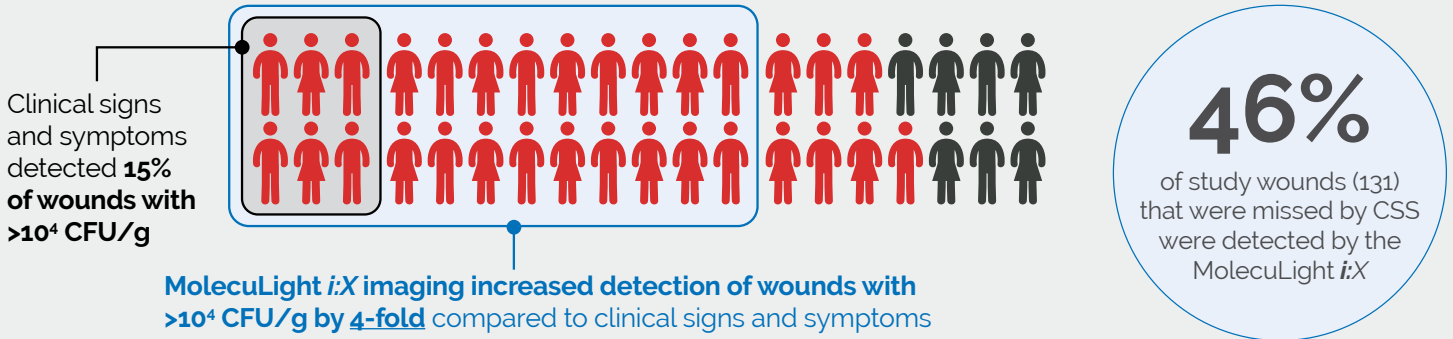


The device (MolecuLight *i:X*) is positioned parallel to the wound and the environment is made dark prior to capturing a fluorescence image. The safe violet light from the device causes porphyrin and pyoverdine-producing bacteria at loads  $>10^4$  CFU/g to emit red or cyan fluorescence. Tissue fluoresce green.

## Results

At bacterial loads  $>10^4$  CFU/g, delayed wound healing is observed<sup>1,2</sup>

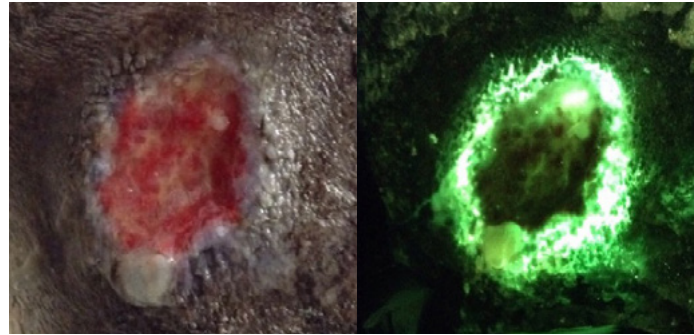
**82% of study wounds had bacterial loads  $>10^4$  CFU/g, 18% of wounds had  $<10^4$  CFU/g**



1. Caldwell et al. Surg Clin NA, 2020; 2. Xu et al. Diabetes Care, 2007 \*FLAAG - Fluorescence imaging Assessment And Guidance Trial

## Example Images

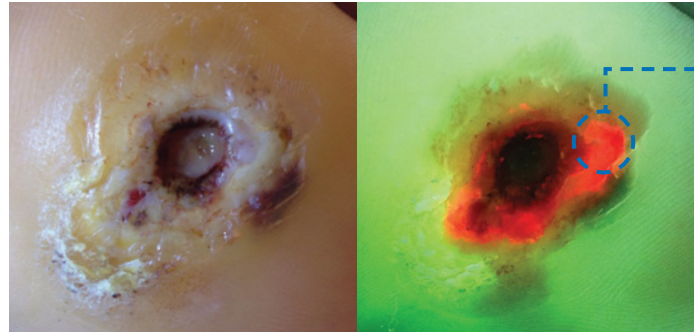
**MolecuLight i:X images of a VLU with cyan fluorescence (right).** A biopsy confirmed load of  $10^5$  CFU/g



Standard Image

Fluorescence Image

**MolecuLight images of a DFU with red fluorescence (right).** A biopsy confirmed load of  $10^5$  CFU/g



Standard Image

Fluorescence Image

In **>80%** of wounds positive for red or cyan fluorescence indicative of high bacterial loads, fluorescence was detected outside of the wound bed, a region typically overlooked during assessment.

## Clinical Impact

Using the MolecuLight i:X resulted in changes to treatment plan in

**69%**  
of wounds

**% of Study Wounds for Which Information Provided by Fluorescence Imaging (FL) for Detection of High Bacterial Loads Impacted:**

Wound Assessment **79%**

Wound Bed Preparation **85%**

Antimicrobial Stewardship **53%**

Debridement **48%**

## Clinical Insights

Assessment of clinical signs and symptoms failed to detect **85% of wounds with high bacterial burden ( $>10^4$  CFU/g).**

Using the MolecuLight i:X at point-of-care during routine wound assessment:

- **Improved detection of high bacterial burden across all wound types and informed of bacterial location**
- **Influenced multiple aspects of wound care from assessment to treatment planning**

The immediate, actionable information on presence of high bacterial loads provided by the MolecuLight i:X helped clinicians to detect and address bacterial burden at point-of-care.