



Request New ICD-10-PCS Codes for the MolecuLight *i:X*[®] Procedure

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ML *i:X* Procedure is Applied Inpatient or Outpatient

Use of point-of-care ML *i:X* Procedure in an Operating Room.

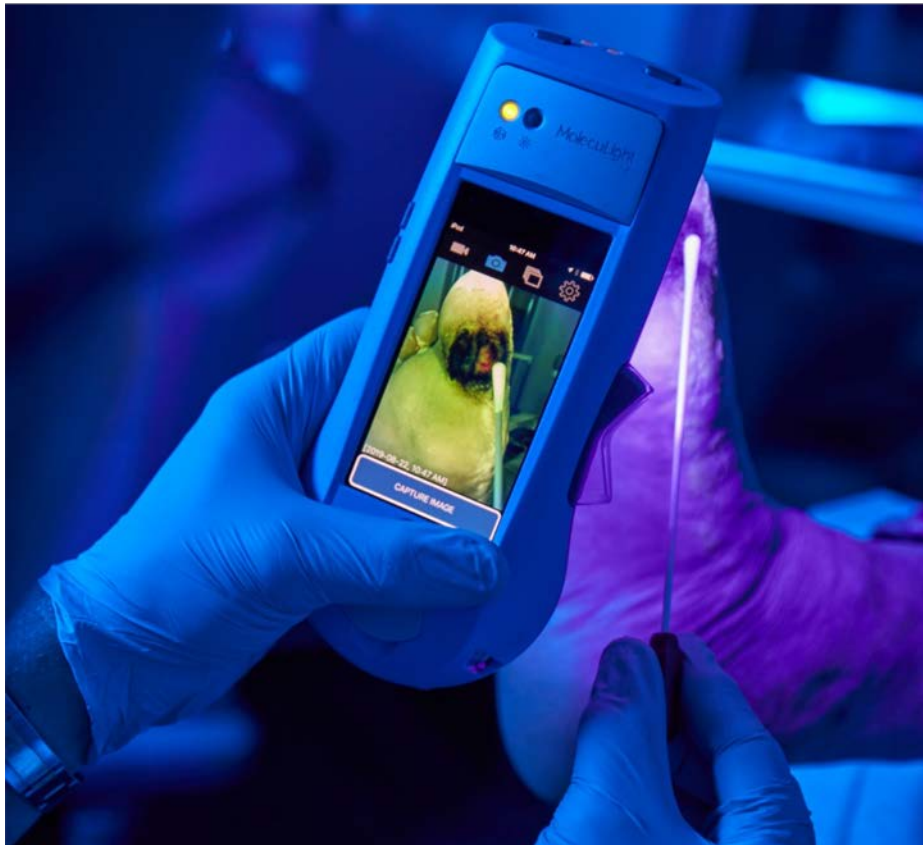
The DarkDrape is Provided When Room Lighting Cannot be Extinguished



MolecuLight *i:X* Separate Procedure



Provides real-time evidence of bacterial presence, location and load,; changing treatment planning, improving graft survival, leading to improved wound healing Xu, et. al. Diabetes Care. 2007; 30:(2):378-80



Documentation of bacteria presence in the wound

Know where bacteria are located and load

Less lab testing, no wait, pathogens immediately identified at POC

Appropriate treatment planning

Aids Antimicrobial stewardship

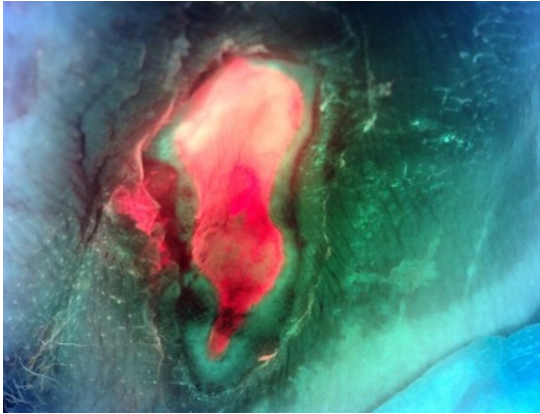
MolecuLight i:X Procedure Red Fluorescence

Red fluorescence indicates moderate-to-heavy loads of bacteria¹ (levels that delay healing²)

Standard Image



Fluorescence Image



Heavy growth *Citrobacter koseri*

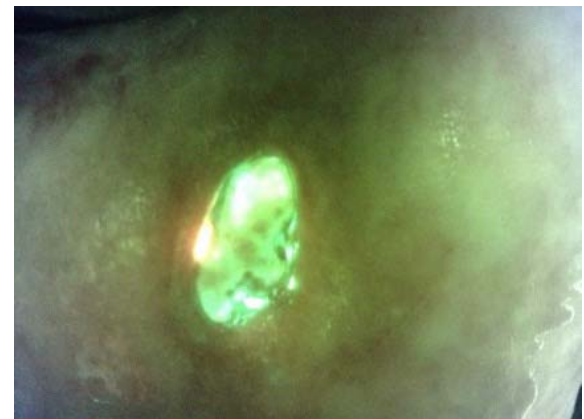
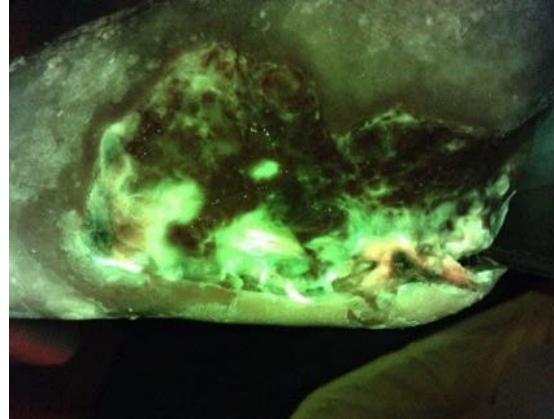
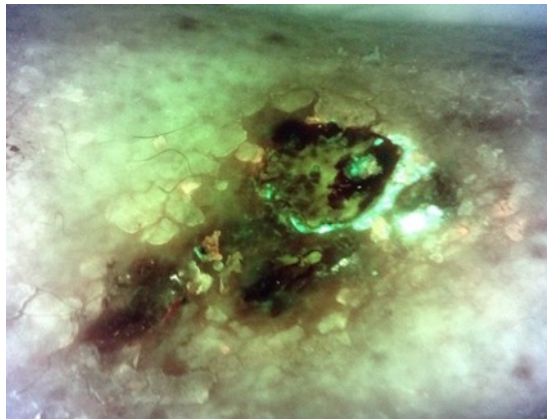
Heavy growth Mixed coliforms, mixed anaerobes

Heavy growth Mixed bacteria

1. Rennie MY et al., Diagnostics 2019; ²Xu Diabetes Care 2007.

MolecuLight i:X Procedure Cyan Fluorescence

Cyan fluorescence visualized using the fluorescence image procedure is specific to *Pseudomonas aeruginosa*^{1,2}.



Heavy growth *Pseudomonas aeruginosa*

Heavy growth *Pseudomonas aeruginosa*, Heavy growth of *Staphylococcus aureus*

Heavy growth *Pseudomonas aeruginosa*, Heavy growth mixed anaerobic bacteria

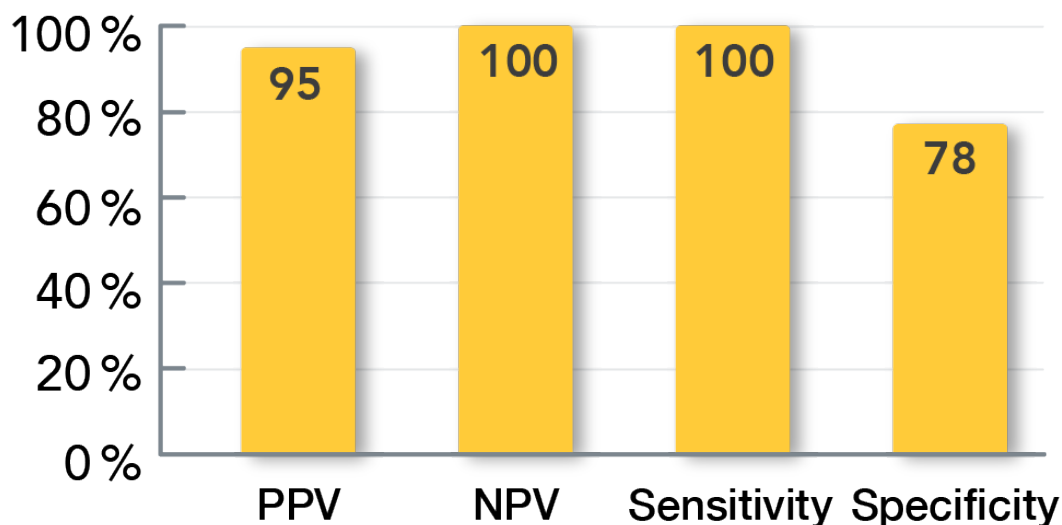
1. Rennie MY *et al.* Diagnostics, 2019
2. Raizman. R Presented at EWMA 2018.

MolecuLight *i:X* Procedure Results

Clinical Evidence Visualizing Fluorescence from Bacteria



- In an independent clinical study¹ of 50 swabs (n=33 patients) taken and assessed by culture analysis.
- High diagnostic accuracy of fluorescence images acquired using ML *i:X* procedure in predicting presence of bacteria at clinically significant loads.



¹Hurley et al, J of Wound Care 2019

MolecuLight i:X Procedure: ICD-10-PCS



ONLY real time Point of Care (POC) procedure reporting bacteria presence, location and load per anatomic site.

KNOW the bacterial presence and pathogenicity beyond CSS

VALIDATE INFECTION FREE : Fluorescence (FL-) indicates **with certainty**¹:
≤10⁴ CFU/g and absence of bacteria that could prevent wound healing.

Multicenter 60-patient study, red FL from bacteria had a **positive predictive value of 100%** for detecting loads of ≥10⁴ CFU/g (moderate-to-heavy growth)²

confirmed by microbiological analysis (qPCR or culture).

consistent across all clinicians, study sites, sampling methods (curettage or biopsy), and microbiological analytic techniques.

¹Hurley et al, J of Wound Care 2019; ²Rennie, et. al. Journal of Wound Care 2017; 26:452-460.

MolecuLight *i:X* Procedure: ICD-10-PCS

Data Changes Treatment Planning



U.S. Study 2 physicians 17 VLUs/2 DFUs Bacteria $\geq 10^4$ CFU/g
MolecuLight *i:X* + CSS compared to CSS Standard of Care

ML *i:X* sensitivity 72% versus **22% for CSS**

ML *i:X* accuracy 74% versus 26% for CSS (p=0.002)

- **47% of wound were incorrectly diagnosed by CSS**
- MolecuLight *i:X* changed treatment plan **in 73% of wounds.**

Identification of infection in the wound today is wrong 80% of the time.

Serena, et.al. Journal of Wound Care 2019 Vol 28(1)

Routine Process to Identify Infection in Wounds



Clinicians visually inspect wounds for CSS Poor Results



Covert signs

- ☐ Hypergranulation
- ☐ Bleeding, friable granulation
- ☐ Epithelial bridging and pocketing in granulation tissue
- ☐ Wound breakdown and enlargement
- ☐ Delayed wound healing beyond expectation
- ☐ New or increased pain
- ☐ Increasing malodor

Classic signs

- ☐ Erythema
- ☐ Local warmth
- ☐ Swelling
- ☐ Purulent discharge
- ☐ Delayed wound healing beyond expectations
- ☐ New or increasing pain
- ☐ Increased malodor

Presence of 3 or more signs listed above indicates infection

MolecuLight i:X Paradigm Shift Identifies Bacteria in Wounds



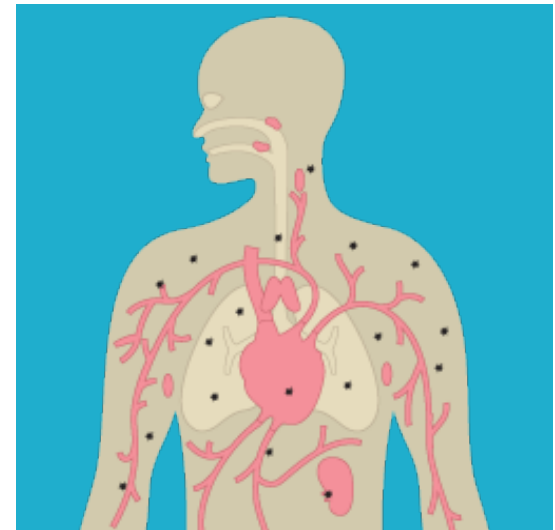
Identifying bacteria in wounds leads to appropriate wound bed preparation, delivers reduced time to healing, improves wound bed preparation required for NPWT and Graft Placement



Delayed healing
(at loads $\geq 10^4$ CFU/g)¹



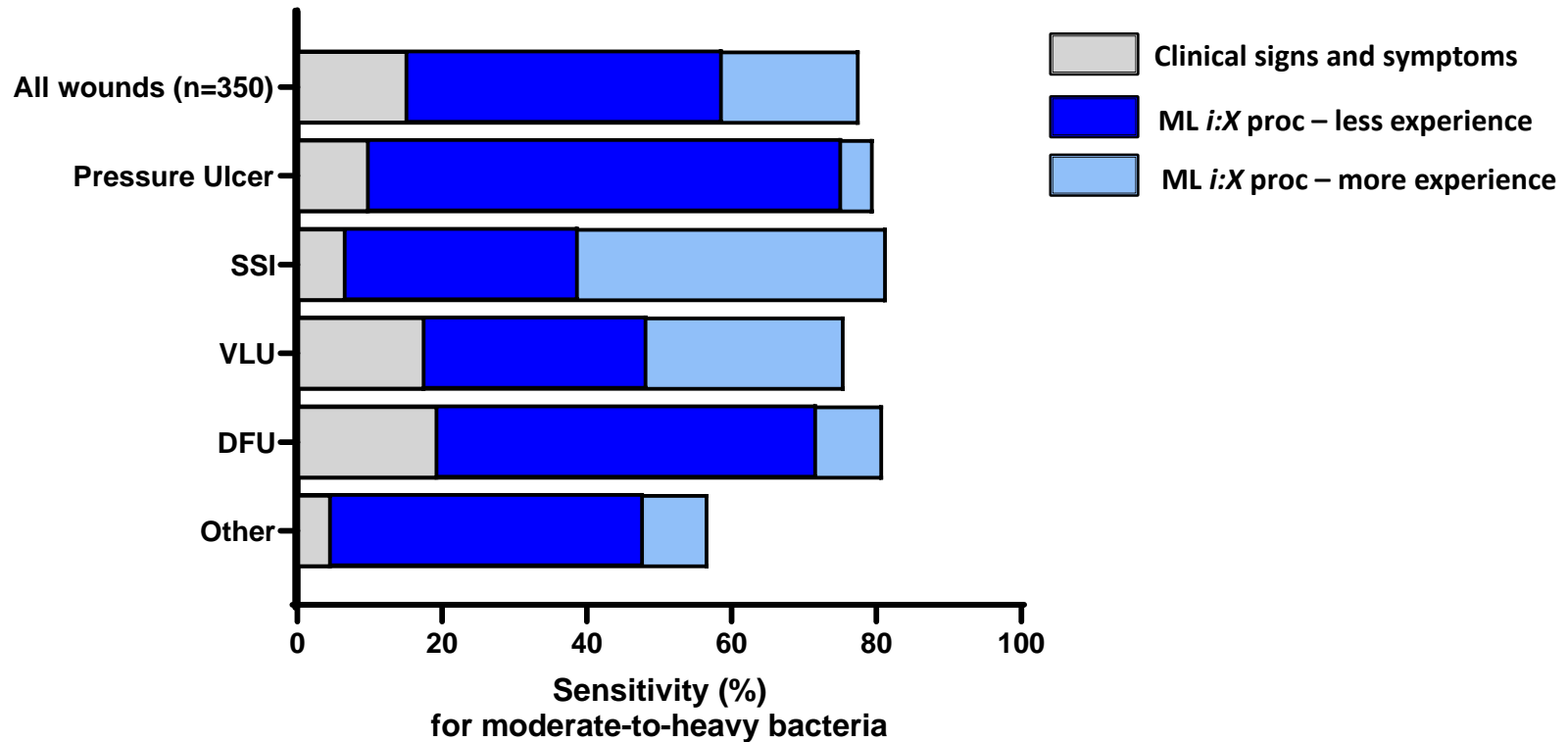
Formation of biofilm
(Bacteria shielded from
antibiotic effects, hard to
eradicate²)



Systemic Infection

1. Xu et al. *Diabetes Care*, 2007; 2. Attinger & Wolcott, *Adv Wound Care* 2012

MolecuLight *i:X* Sensitivity is Increased with Experience Using Procedure



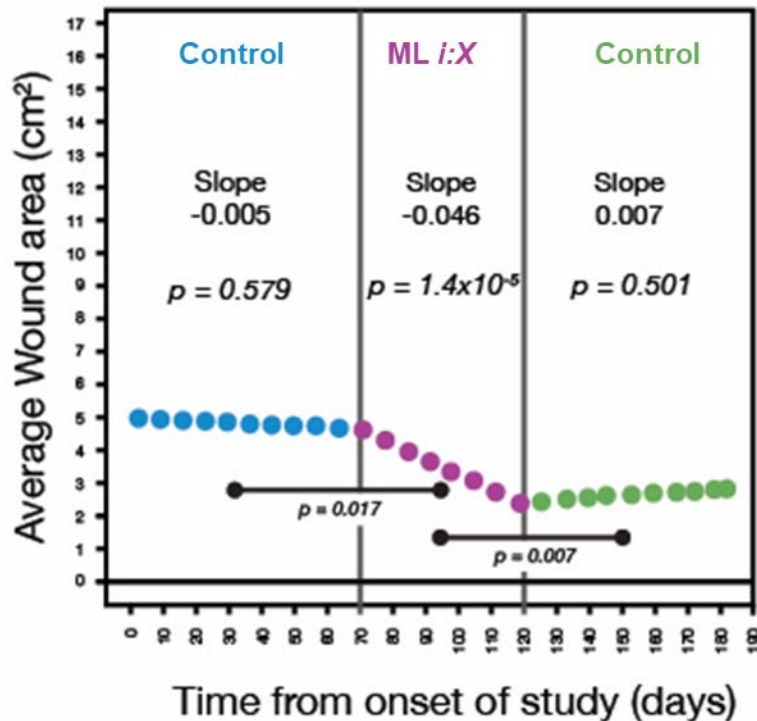
Sensitivity to detect moderate-to-heavy loads of bacteria was increased when clinicians had more experience using the ML *i:X* procedure (including interpretation).

ML i:X Procedure Improves Patient Outcomes

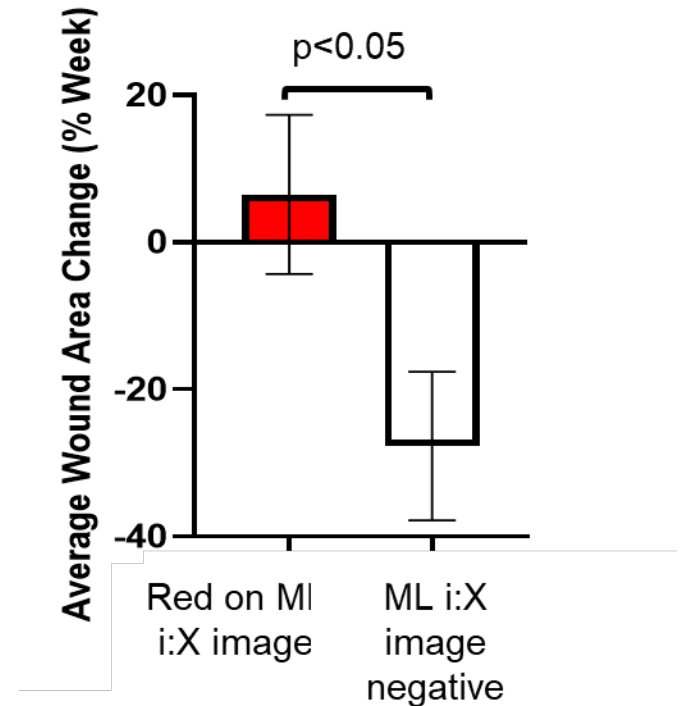


- **Two longitudinal studies** assessing effects of this procedure on wound area reduction reported^{1,2}:
 - **improvements in wound area reduction (p=0.017)**
 - **non healing wounds switched to a healing trajectory**

DaCosta (2015):



Cole (2019) 12-week study:



¹DaCosta R, PLoS One 2015; ²Cole W et al, Presented at SAWC Fall 2019

MolecuLight *i:X* Typical Patient and Procedure



Patients **with** an acute or chronic wound often have comorbidities. Having real-time knowledge of bacterial presence, location and load at the point of care aids treatment decisions, driving improved outcomes.

Typical patient 1 or more nonhealing wounds w/ pain & warmth

ML *i:X* reports FL, location, load & pathogens $>10^4$ CFU/g

Tx changes 55% of the time¹; e.g. delaying closure by secondary intention^{2,3}.

Evidence reports improved patient care, less graft failure, and reduced time to healing^{4,5}

¹Serena et al, Presented at SAWC Fall 2019; ²Aung B, Today's Wound Clinic 2019; ³Jeffery Proceedings of SPIE 2019; ⁴DaCosta R, PLoS One 2015; ⁵Cole W et al, Presented at SAWC Fall 2019

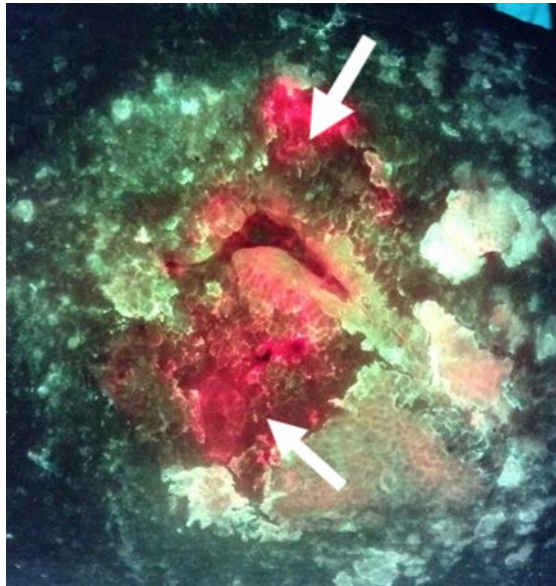
MolecuLight *i:X* Procedure: ICD-10-PCS *Data Changes Treatment Planning Leading to Healing Trajectory*



ML *i:X* Standard image



ML *i:X* Procedure



CSS assessment was negative.

ML *i:X* procedure indicated lots of bacteria in wound.

This prompted addition of an antimicrobial bandage on the wound.

Microbiology confirmed heavy growth (5.4×10^7 CFU/g) of bacteria.

MolecuLight *i:X* Procedure: ICD-10-PCS Needed

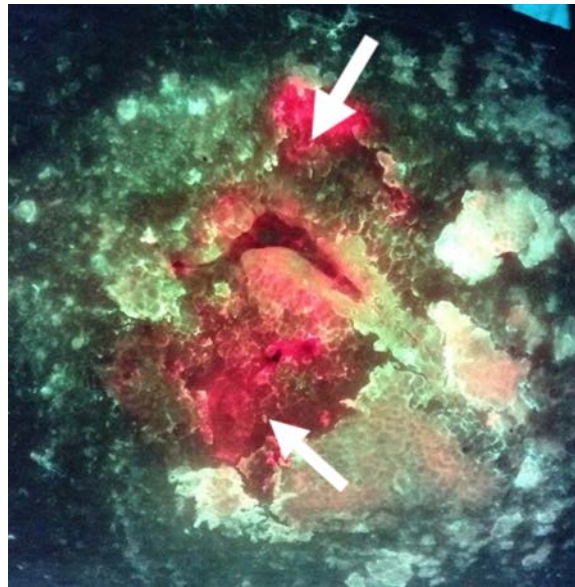
Paradigm Change in Wound Care Treatment and Planning



ML *i:X* Standard image



ML *i:X* Procedure



Microbiology confirmed heavy growth (5.4×10^7 CFU/g) of bacteria.

- ▶ **New Novel Procedure.**
- ▶ **Changes treatment in more than 70% of patient cases.**
- ▶ **Substantially improve longitudinal data analysis for outcome**

Thank you for your time