

# MolecuLight i:X for wound imaging

Medtech innovation briefing

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## Summary

- The **technology** described in this briefing is MolecuLight i:X. It is for imaging wounds to identify fluorescent bacteria.
- The **innovative aspects** claimed by the company are that this is the only point-of-care, handheld device able to visualise fluorescent bacteria and measure wound surface area (with the MolecuLight WoundStickers add on).
- The intended **place in therapy** would be in addition to current standard of care in people with any type of acute or chronic wounds.
- The **main points from the evidence** summarised in this briefing are from 7 observational studies including 177 adults and 10 children in secondary care and outpatient settings. They show that MolecuLight i:X can detect wound bacteria at a comparable level to microbiology swabs.

- **Key uncertainties** around the evidence or technology are that there is limited evidence to show whether MolecuLight i:X reduces wound closure time or improves antibiotic stewardship.
- The **cost** of MolecuLight i:X is £7,500 per unit (excluding VAT). The **resource impact** would be in addition to standard care, the cost of which ranges from £698 to £5,976 per person depending on the types of wound. This could be offset if there are patient benefits such as reduced closure time of chronic wounds. There is no published evidence to support these claims.

## The technology

MolecuLight i:X (MolecuLight Inc) is a handheld imaging device to detect fluorescent bacteria in wounds. It has a touch-sensitive, colour LCD screen and a rechargeable battery. It can capture real-time images and videos in both standard imaging mode and fluorescence imaging mode. A switch on the device allows the user to change between the modes. The best distance for imaging is 8 cm to 12 cm from the wound. The fluorescent images are visualised at the point of care and are designed to identify fluorescent bacteria. If treated, this may help wound closure. MolecuLight i:X detects fluorescent bacteria at levels of  $10^4$  colony-forming units/g or higher on a quantitative scale, or predominantly moderate-to-heavy growth on a semi-quantitative scale. It can also measure wound length, width and area. WoundStickers are placed on opposite sides of the wound to detect the wound border.

MolecuLight i:X emits a precise wavelength of violet light. This interacts with the wound tissue and bacteria. It causes the wound and surrounding skin to emit a green fluorescence (because of collagen), and potentially harmful bacteria to emit a red or cyan fluorescence (because of the production of porphyrins or pyoverdine by bacteria). These fluorescence signals are captured by MolecuLight i:X and displayed on a screen. All images and videos can be browsed in the image library.

Accessories for MolecuLight i:X include:

- WoundStickers (2 WoundStickers are placed next to the wound to measure wound surface area. This can be used in standard imaging mode).
- DarkDrape including a built-in adapter (for optimal imaging when room lights cannot be turned off. The adapter device connects DarkDrape to MolecuLight i:X).

- Optical lens wipes are used to clean the display screen and optical components. There are 5 lens wipes included with the device.

Overall, MolecuLight i:X is to help wound assessment, by focusing cleaning, debriding and swabbing of the wound where bacteria are located. It is also intended to improve antibiotic stewardship and optimise the timing of treatment for wound infection.

## Innovations

The company claims that MolecuLight i:X can quickly, safely and easily visualise fluorescent bacteria and measure wound surface area at the point of care. The company claims no other devices can visualise bacteria in this way through a handheld device. MolecuLight i:X may lead to better informed clinician decisions, improved antimicrobial stewardship and patient engagement.

## Current care pathway

The standard of care involves sampling for culture and using systemic or oral antibiotics in line with local protocol, alongside antimicrobial barrier dressings. When prescribing an antimicrobial, microbiological samples should be taken before prescribing and choice of antimicrobial reviewed after antimicrobial results. For non-severe infections, it may be appropriate to withhold antimicrobials until microbiological sample results are back.

If a diabetic foot infection is suspected and there is a wound, a soft tissue or bone sample from the base of the debrided wound should be sent for microbiological examination. If this cannot be done, a deep swab should be taken because it could give useful information about the choice of antibiotic.

The company states that MolecuLight i:X can be used at any point of the wound management pathway, giving real-time information at the point of care. The technology can also be a supporting tool for diagnosing wound infection in addition to clinical signs and symptoms.

The following guidelines have been identified as relevant to this care pathway:

- [NICE guideline on antimicrobial stewardship: systems and processes for effective antimicrobial medicine use](#)

- [NICE guideline on diabetic foot problems: prevention and management.](#)

## Population, setting and intended user

The company states that MolecuLight i:X is for people with any acute or chronic wound. Specialities in which the device may be used include tissue viability, podiatry, plastic surgery, burns and in acute and community wound clinics.

MolecuLight i:X could be used in acute settings in secondary care, and also in the community. MolecuLight i:X is for trained healthcare professionals, including tissue viability nurses, GPs, podiatrists, and surgeons (for example, vascular and general surgeons).

Training is needed to use MolecuLight i:X and is included in the cost of the device.

## Costs

### Technology costs

MolecuLight i:X costs £7,500 (excluding VAT). The expected life cycle of the product is 2 years. The company lists several options to reduce the price, including:

- volume discounts
- product bundling including device and consumables
- a leasing model.

MolecuLight i:X comes with a standard 1-year warranty. An extended warranty can be purchased from the company. MolecuLight i:X comes with WoundStickers to measure 1,000 wounds. Additional WoundStickers are available separately. MolecuLight DarkDrape is a single-use disposable device. This is an optional extra and is available separately.

### Costs of standard care

The company cites sources [Nussbaum et al. \(2017\)](#) and [Stockl et al. \(2004\)](#) for estimates of costs of treating infected wounds. These range from \$4,345 (USD) to \$6,717 (USD), equivalent to around £3,317 to £5,127. In the NHS, the cost for each healed wound ranged from £698 to £3,998 per person and that of an unhealed wound ranged from £1,719 to

£5,976 per person ([Guest et al. 2016](#)).

## Resource consequences

The company states that MolecuLight i:X was introduced to the UK in March 2018, with 100 devices used across the NHS and private healthcare.

MolecuLight i:X costs more overall, but could lead to downstream cost-savings if there are benefits such as reduced closure time for chronic wounds.

Using the MolecuLight i:X imaging device does not need significant changes to facilities. The device is portable. The DarkDrape accessory can be easily attached to the device in clinical settings in which room lights cannot be easily switched off.

## Regulatory information

MolecuLight i:X is a CE-marked class IIa medical device.

Add-ons including MolecuLight DarkDrape, Wound Stickers and Optical lens wipes, are CE-marked class I medical devices.

## Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

MolecuLight i:X is for any patient with an acute or chronic wound. Older people, people with diabetes and those with restricted mobility are more likely to have chronic or non-healing wounds. Age and disability are protected characteristics under the Equality Act 2010.

MolecuLight i:X needs the user to be able to distinguish between green and red. The company states that the device should not be used by individuals confirmed to be colour blind. Colour blindness may be considered as a disability under the Equality Act 2010.

# Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting [mibs@nice.org.uk](mailto:mibs@nice.org.uk).

## Published evidence

Seven observational studies are summarised in this briefing, involving 177 adults and 10 children in secondary care and outpatient settings. Results show that MolecuLight i:X can detect wound bacteria at a comparable level to microbiology swabs.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

## Overall assessment of the evidence

Overall, the evidence base for MolecuLight i:X is of low methodological quality. Observational study designs give low-quality evidence, sample sizes are small, and there are a limited range of outcomes. There is a lack of evidence on wound closure times and the effect on antibiotic usage.

Large, UK-based multicentre randomised controlled trials are needed, comparing MolecuLight i:X with standard care. Relevant outcomes would include bacterial growth on culture and whether this corresponded to findings using MolecuLight i:X, average wound closure time, and number of antibiotics used.

### Blackshaw and Jeffery (2018)

#### Study size, design and location

[A single-centre prospective observational study in the UK of 14 patients](#) (with a total of 17 wounds) presenting to outpatient dressings clinics.

## **Intervention and comparator(s)**

Intervention: MolecuLight i:X imaging device.

Comparator: clinical signs and symptoms of infection (CSS), microbiological swabs.

## **Key outcomes**

Out of 17 wounds, 8 were positive for bacterial growth on microbiological culture and all 8 were positive for bacteria according to fluorescence imaging. One wound was positive for bacteria by fluorescence imaging with negative microbiological results and CSS. Three patients did not complain of, or display CSS, but fluorescence photos and swab results confirmed bacterial growth. All 6 patients that did exhibit CSS had photos and swab results confirming positive bacterial growth.

## **Strengths and limitations**

A UK-based study that is generalisable to the NHS. A single-centre observational study gives low-quality evidence. Small sample size, which limits the reliability of results. Limited reporting of outcomes with no statistical analysis of results.

## **Blumenthal and Jeffery (2017)**

### **Study size, design and location**

A pilot study in the UK of 20 patients with burn wounds presenting between April and July 2016.

### **Intervention and comparator(s)**

Intervention: MolecuLight i:X imaging device.

Comparator: CSS of infection, microbiology swabs.

### **Key outcomes**

Out of 20 patients, 16 (80%) showed growth of bacteria in swabs and MolecuLight i:X imaging.

Two patients did not have CSS but images and swabs showed bacterial presence and 1 patient had CSS when the images and swabs were negative.

### **Strengths and limitations**

UK-based study that is generalisable to the NHS. A single-centre study limits the reliability of findings. No statistical analysis of results. There is a good range of outcomes, including which antimicrobial intervention was given.

## **Chew et al. (2019)**

### **Study size, design and location**

A single-centre observational study in the UK of 31 patients (with a total of 35 wounds) attending a hand trauma unit over 4 weeks.

### **Intervention and comparator(s)**

Intervention: MolecuLight i:X imaging device.

Comparator: CSS, microbiological swabs.

### **Key outcomes**

Autofluorescence imaging correlated with clinical signs and wound swab results for 34 wounds (97.1%). In 1 case, the clinical assessment and autofluorescence imaging showed positive signs of infection but the wound swabs were negative.

### **Strengths and limitations**

A UK-based study that is generalisable to the NHS. A single-centre study and small sample size limit the reliability of results.



## Hurley et al. (2019)

### Study size, design and location

A single-centre prospective observational study in Ireland of 33 patients (43 swabs) in an outpatient plastic surgery wound care clinic.

### Intervention and comparator(s)

Intervention: MolecuLight i:X imaging device.

Comparator: microbiological swabs.

### Key outcomes

There were 41 out of 43 swabs (95.3%) that were positive for bacterial growth. MolecuLight i:X had a sensitivity of 100% and specificity of 78% when identifying pathological bacteria presence in wounds. The positive predictive value (PPV) was 95.4% and the negative predictive value was 100%. There was a 100% sensitivity and specificity in detecting *Pseudomonas spp.* Overt signs of infection were identified in 7 patients, and a 1-week course of antibiotics was prescribed. After 2 weeks, all fluorescence and microbiological swabs were negative.

### Strengths and limitations

Relevant outcomes were reported. Wound types were varied which helps to show use of MolecuLight i:X for a wide range of indications. A single-centre observational study gives low-quality evidence.

## Farhan and Jeffery (2020)

### Study size, design and location

A single-centre observational study in the UK of 10 children with burn wounds (total 15 wounds with 16 observations).

## Intervention and comparator(s)

Intervention: MolecuLight i:X imaging device.

Comparator: CSS of infection, microbiological swabs.

## Key outcomes

The presence or absence of bacterial fluorescence on images was consistent with CSS of infection in 87.5% of cases (14/16). In the other 2 cases, MolecuLight i:X images detected red (bacterial) fluorescence in the absence of any signs or symptoms, with both cases confirmed bacterial positive with swabs.

The presence or absence of bacterial fluorescence on images was consistent with culture analysis in 81% of cases (13/16) and no false negatives were detected. The remaining 3 wounds were fluorescence and CSS positive in both observations. These 3 wounds were swabbed but not targeting the area of bacterial fluorescence and so may have been missed.

Reports about using the device with children were positive. No adverse events were reported.

## Strengths and limitations

A single-centre observational study gives low-quality evidence. A small sample size limits reliability of results. Most patients in the study were treated with topical antimicrobial agents before taking swabs, which may have resulted in false-negative cultures.

## Rennie et al. (2017)

### Study size, design and location

A non-randomised single-blind clinical trial in the US and Canada of 60 patients with chronic wounds (47 diabetic foot ulcers, 12 venous leg ulcers and 1 amputation) showing regions of red fluorescence.

The study consists of 2 arms: arm 1 was a multisite clinical trial in the US, arm 2 was a post-market clinical follow-up trial in Canada.

## **Intervention and comparator(s)**

Intervention: MolecuLight i:X.

Comparator: quantitative polymerase chain reaction (PCR) of biopsy samples (arm 1) or semi-quantitative culture analysis of curettage samples (arm 2).

## **Key outcomes**

In arm 1 of the study (30 wounds), PCR analysis of wound tissue biopsies from areas of red fluorescence resulted in a PPV of 100%, with a total bacterial load of  $10^4$  colony-forming units (CFU)/g or higher. In arm 2 of the study (30 wounds), semi-quantitative culture analysis of curettage scrapings from regions of red fluorescence resulted in a PPV of 100%, with predominantly moderate or heavy bacterial growth.

## **Strengths and limitations**

A sample size power calculation was performed for each arm of the study. Study included a range of different wound types, which increases reliability of results and generalisability to different wound types. The study was not done in UK and so is not generalisable to an NHS setting. The study author is an employee of the company.

## **Serena et al. (2019)**

### **Study size, design and location**

A prospective, single-blind, single-centre clinical trial in the US of 19 patients (17 venous leg ulcers and 2 diabetic foot ulcers) presenting at an advanced outpatient wound research clinic.

### **Intervention and comparator(s)**

Intervention: MolecuLight i:X.

Comparators: CSS, microbiological assessment of biopsies.

## Key outcomes

MolecuLight i:X with CSS significantly improved sensitivity (22% compared with 72%) and accuracy (26% compared with 74%) for identifying wounds with moderate-to-heavy bacterial loads ( $10^4$  CFU/g or higher) compared with CSS alone ( $p=0.002$ ). Clinicians reported that overall patient care was improved by fluorescence imaging assessment in 18 out of 19 cases (95%), including identification of wounds incorrectly diagnosed by CSS (47% of study wounds) and treatment plan modifications guided by fluorescence (73% of study wounds). Antimicrobial stewardship decisions were guided by fluorescence imaging in 47% of cases.

## Strengths and limitations

A comparative study helps to compare results with standard care. There is a good range of outcomes, including consideration of antibiotic usage and management decisions. A single-centre observational study gives low-quality evidence. A small sample size limits reliability of results. Not done in the UK so not generalisable to the NHS. The trial was sponsored by the company.

## Recent and ongoing studies

- [MolecuLight i:X in wound healing](#). ClinicalTrials.gov identifier: NCT03270904. Status: unknown. Indication: ulcer foot. Last update posted: 24 January 2018. UK. Devices: MolecuLight i:X fluorescence imaging.
- [Evaluating surface area reduction using MolecuLight i:X imaging device](#). ClinicalTrials.gov identifier: NCT03181568. Status: unknown. Indication: wound, wound infection. Last update posted: 9 June 2017. UK. Devices: MolecuLight i:X imaging device.
- [Comparing wound area reduction of non-healing DFUs using MolecuLight i:X versus standard of care \(WAR\)](#). ClinicalTrials.gov identifier: NCT04207099. Status: recruiting. Indication: non-healing diabetic foot ulcer. Last update posted: 6 March 2020. Devices: MolecuLight i:X imaging.
- [Presence of fluorescence signature to predict graft failure using MolecuLight i:X](#). ClinicalTrials.gov identifier: NCT04185636. Status: enrolling by invitation. Indication: skin graft failure. Last update posted: 6 March 2020. Devices: MolecuLight i:X imaging device.

- Evaluation of MolecuLight i:X as an adjunctive fluorescence imaging tool to clinical signs and symptoms for the identification of bacteria-containing wounds.  
ClinicalTrials.gov identifier: NCT03540004. Status: active, not recruiting. Indication: wound. Last update posted: 6 March 2020. Devices: MolecuLight i:X Imaging.

## Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Five experts were familiar with or had used this technology before.

## Level of innovation

All 5 expert commentators agreed that the technology is novel. One commentator noted MolecuLight i:X is innovative in its concept and design compared with standard wound care. Four commentators were not aware of other devices that could visualise bacteria in real time. Two commentators thought that MolecuLight i:X may lead to antibiotics prescribing for asymptomatic wounds.

## Potential patient impact

Improvements in how well patients take their prescribed treatment and wound healing were the main potential benefits identified by 3 expert commentators. Patients could observe wound healing by looking at the images themselves, which is a useful tool to explain the need for antibiotics. Four commentators thought that MolecuLight i:X could lead to change in current wound care, especially for people with infected wounds that do not show any clinical signs, by detecting infection earlier and providing timely treatment. The expert commentators agreed that the technology would be of most benefit for people with chronic or non-healing wounds, and those with diabetic foot ulcers, leg ulcers, surgical wounds and skin grafts.

## Potential system impact

Reducing the cost for wound care was identified as a key benefit to the healthcare system.

Possible improvements in efficiency of wound management and wound healing (that is, bacterial change in the wound) were also identified by the commentators. Four expert commentators thought using MolecuLight i:X would reduce the cost in wound care because of a potential reduction in the number of dressings used and antibiotics prescribed. Two commentators thought there would be little change to current facilities or infrastructure. Experts thought that training would be needed to ensure correct use of the technology and accurate interpretation of the results.

## General comments

All commentators thought MolecuLight i:X would be used as an add-on intervention to current standard care for wound management. None of the experts were aware of any safety issues but 1 commentator noted people who are colour blind will not be able to use MolecuLight i:X because they cannot interpret the images correctly. The main barrier to adoption identified by 2 commentators was the lack of evidence on patient and system benefits of the technology.

## Expert commentators

The following clinicians contributed to this briefing:

- Richard Leigh, consultant podiatrist, Royal Free London NHS Foundation Trust, did not declare any interests.
- Nadine Price, care pathway lead for acute podiatry, North East London NHS Foundation Trust, did not declare any interests.
- Sara Rahma, clinical research fellow in vascular surgery, Leeds Teaching Hospitals NHS Trust, did not declare any interests.
- Steven Jeffery, consultant burns and plastic surgeon, The Queen Elizabeth Hospital, received travel funding to a conference.
- Henk Giele, consultant plastic surgeon, Oxford University Hospitals, did not declare any interests.

# Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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