

## CombiMark

CombiMark is a Class 1 medical device design company founded in Ireland in 2018. CombiMark was founded to develop products that improve patient outcomes, enhance usability and model a new generation of medical devices. The company works directly with clinical partners to identify opportunities to develop a suite of products that support clinical excellence. The company's flagship product is SideSafe R/L, a single-use X-ray side marker made from a patented range of sustainable materials.



## About Health Innovation Hub Ireland

Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health, supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise.

We offer companies the opportunity for pilot and clinical validation studies and the health service access to innovative products, services and devices that they may not otherwise be exposed to.

HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways and outcomes.



## The Healthcare Challenge

It is globally accepted best practice that all radiographic images must display a correct anatomical side marker to ensure R/L fidelity. These radiographic markers are the most frequently handled objects in the radiology department. The same markers are used with every patient, and are kept in the radiographer's pockets when not utilised, and are never or rarely cleaned. Issues include:

- Radiographers R and L, touch marker, touch patient.

- Risk of blind spot infection
- Some radiographers do not use their markers – lose them or can't put a finger on them and rely on retrospectively digitally marking sites when uploading images, which is not best practice.

Disposable markers are available but they are expensive and some contain materials unsuited to use in healthcare settings such as latex.

## The Healthcare Solution

Consultant Radiologist OLCH, Dr Aisling Snow saw an opportunity to develop a competitively priced disposable marker made from more appropriate biodegradable materials. Dr Snow partnered with her sister Fiona Snow, an industrial designer, to form CombiMark, an Enterprise Ireland HPSU and TCD spin out that produces SideSafe disposable X-ray markers. These markers are the first that are sustainably disposable and are ground-breaking in medical device design being 100 per cent plastic-free and made with a low-intensity manufacturing process.

SideSafe markers

- Disposable markers (letters 'L' 'R') for X-ray - no metal, no plastic.
- Use single letters per patient, addresses infection control/cross contamination.
- Improve patient safety by ensuring that anatomical marking is undertaken at the bedside and not retrospectively when uploading images.
- Reduce Infection and improve r/l fidelity.

# Market Potential

The market potential for the product – a world first in its field as a sustainably disposable device is significant, considering the direction of global healthcare waste disposal. SideSafe markers are sustainably disposable as it is 100 per cent plastic-free and made with a low-intensity manufacturing process. Once disposed of, SideSafe markers completely decompose.

More than 2.4 billion X-rays are performed worldwide each year, with 200 million performed in the United States alone. Disposables are appropriate in numerous clinical settings but sustainability is becoming an issue with new guidelines being issued. It is a challenge to produce disposables sustainably to meet growing needs and this is a key Combimark market focus.

## HIHI Role

HIHI designed a single-phase usability study across two sites – OLCH and St James', with HIHI gathering feedback to inform product development. There were 31 participants in total across the two sites, all radiographers with various levels of experience.

The first phase evaluated the prototype letters over a five-day period. 500 markers were included, with four to five radiographers using the product. As part of the work HIHI developed and disseminated a formalised questionnaire, which each participant radiographer (with an assigned number rather than name) completed after Study 1.

HIHI attended OLCH and St James' information sessions following an OLCH 'expression of interest' internal meeting. HIHI provided overall project management – Stage 1 and 2 and was the liaison between key personnel. HIHI managed data capture – design and delivered two short online feedback questionnaires for radiologists and radiographers. HIHI then completed an independent HIHI report with clinical input for Combimark at close of project.



## Outcome Report

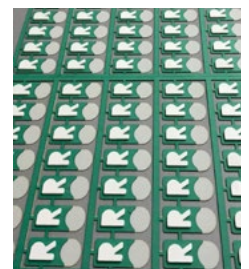
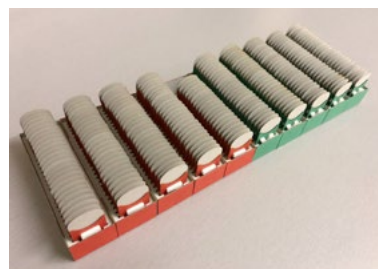
SideSafe markers have four clear clinical benefits:

- **Cleanliness:** current reusable markers have been found to be contaminated (80 per cent) and rarely if ever cleaned (92 per cent). One SideSafe marker for one patient eliminates any opportunity for the spread of infection via X-ray markers.
- **Accessibility:** Reusable markers are underused, with reliance often on digital X-ray marking, which is not recommended best practice. This can actually lead to errors in image reporting. SideSafe makers can be docked in portable X-rays, are clean and safe to take into ICU, and will always be present in the X-ray room ensuring markers are within reach of radiologists
- **Device Regulations 2020:** CE marked Sidesafe meets all of the necessary EU Medical Device Regulations 2020, compared with the unregulated legacy product.
- **Cost benefit:** Infection control and the treatment of hospital-acquired infections bears a significant cost on hospitals and serious risks for patient health. SideSafe protects hospitals from the costs associated with managing infection spread by side markers, and the cost associated with decontamination of reusable markers. In a large Irish hospital more than 100,000 radiographs are taken each year – this is up to 100,000 opportunities for infection to spread via current reusable markers and 100,000 chances for a side safety error to be made if a marker isn't used.

## Testimonial

*HIHI allowed Aisling as a clinician to be a step removed from organising the usability test in both sites, which had the benefit of avoiding any sense of obligation on the radiography services managers and on the radiographers involved. The HIHI study provided a structure and defined workflow for engagement with clinical teams and facilitated the collection and collation of data. The Hub also provided the company with contacts and introductions to other entrepreneurs and people of relevance in clinical sites, as well as facilitating media engagement.*

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