

Primary Endpoint Achieved

Within-Subject Analysis, n=206 Device-Arm Participants (p=.005)

Claire demonstrated ability to reduce diseased margins after standard of care (SOC), potentially reducing re-excisions.

20% relative reduction in patients with residual disease remaining after standard of care

7 of 35 patients with residual disease after SOC were completely cleared by Claire

Positive margin rate reduced from 17.0% to 13.6%

35 → 28 patients with residual disease

Statistically significant • p = 0.005 • Super-superiority goal exceeded

96%

Negative predictive value—a high probability that negative Claire-aided margin assessments truly mean no disease *

NPV

91%

Specificity- Claire correctly identifies negative margins with high confidence *

Specificity

61.5%

Combined sensitivity of SOC+ Claire. Use of Claire resulted in a 26.3% relative increase in margin sensitivity over SOC alone.

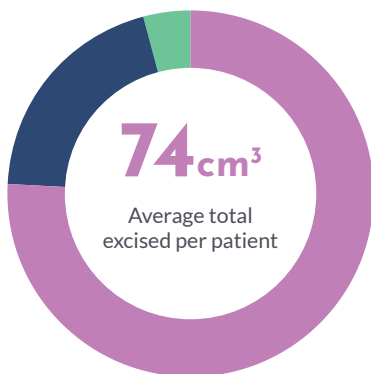
72/117 margins

88.1%

Overall margin-level accuracy of clinical decisions aided by Claire OCT+AI

95% CI: 85.9-90.2

TISSUE VOLUME EXCISED - INDEX BCS (n=206)



- **56.5** 76% Primary Lump
- **14.7** 20% SOC shaves
- **2.8** 4% Claire-directed shaves

Claire shaves = only 4% of total tissue • SOC excised 5.25x more tissue than Claire • SOC took 4x as many shaves

5.25x Less Tissue

Claire excised 5.25x less tissue volume than SOC shaves. Claire-directed shaves accounted for only 4% of total volume excised.

Robust Safety Profile

0 device-related AEs, 0 UADEs; SAEs were rare (<1.2%) with none attributed to the device.

Cosmetic Outcomes Preserved

BREAST-Q scores showed no negative effect on cosmesis across all groups

26 patients Clinically Benefited from Use of Claire

12.6% of patients received direct diagnostic or therapeutic benefit beyond standard of care

7
Complete margin clearance

7
Partial clearance of residual disease

6
Occult disease intercepted

4
Close margin identified (<1 mm)

2
Non-excised disease located with Claire but not excised due to operational constraints

The efficacy of Claire was evaluated only after completion of standard of care (SOC). For more information, refer to <https://clinicaltrials.gov/study/NCT05113927>

The Claire OCT System is an adjunctive tool; it does not replace standard tissue histopathology nor provide a diagnosis. ImgAssist AI does not provide a diagnosis. The Claire OCT system is designed as a human-AI team, where the AI acts as a screening tool and the surgeon provides clinical judgment.

*measure of clinical decisions aided by Claire OCT+AI