

CLINICAL EVIDENCE FROM ENIVO™ PILOT STUDY PAVES THE WAY FOR POTENTIALLY NEW THERAPY

Highlights

- AROA's Enivo™ system is showing promise in the management of 'dead space' after mastectomy.
- To date, six patients (n=10) enrolled in the Enivo™ pilot clinical study have undergone a unilateral mastectomy and completed follow-up care, with no clinically relevant seroma or complications reported

AROA's Enivo™ system is showing promise in the management of 'dead space' after mastectomy, as results emerge from the first clinical study of the device, currently underway in New Zealand. To date, six patients have undergone unilateral mastectomy surgery and had the device implanted. Ten participants are expected to be enrolled in the study.

'Dead space' which refers to the open space created by surgical separation or excision of soft tissue, can lead to a range of secondary complications, such as seromas and haematomas, resulting in complications and extending hospital stay for patients.

The Enivo™ system, developed by AROA, applies vacuum pressure to a surgical site to eliminate surgical dead space and reduce fluid accumulation following surgery.

AROA CEO Brian Ward says: *"The results emerging from the Enivo study are very encouraging. We have now treated six patients and overall, we are very pleased with the way the device has functioned, with no breast seromas forming. We are hopeful that Enivo could pave the way for a new standard of care in a wide range of surgeries where managing dead space is difficult and subsequent complications may lead to poor outcomes for patients and higher treatment costs."*

A seroma is a collection of fluid which builds up and can result in infection, discomfort, poor cosmetic outcomes, and extended hospital stay. Seromas are the most common post operative complication to develop following mastectomy.

Currently, surgeons use surgical drains, adhesives, or quilting sutures to manage dead space and prevent fluid accumulation, but these techniques can be unreliable, and post-operative complications continue to pose significant challenges.

Associate Professor Michelle Locke, who is leading the study, says: *"I am delighted to be involved in the Enivo clinical study, and hopeful that this innovation will make a real difference to patient outcomes."*

Since the study was initiated in Auckland in July 2023, it has been expanded to include a second study site in Whangarei, New Zealand.

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Authorised on behalf of the Aroa Biosurgery Board of Directors by Brian Ward, CEO.



About Aroa Biosurgery:

Aroa Biosurgery is a soft-tissue regeneration company committed to 'unlocking regenerative healing for everybody'. We develop, manufacture, sell and distribute medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. Our products are developed from a proprietary AROA ECM™ technology platform, a novel extracellular matrix biomaterial derived from ovine forestomach. AROA has commercialised four product families based on its AROA ECM technology, targeting chronic wounds, hernia, soft tissue, and breast reconstruction. Over 6 million AROA products have been used globally in a range of procedures to date, with distribution into our key market of the United States via our direct sales force and our partner TELA Bio. AROA has regulatory approvals in more than 50 countries. Founded in 2008, AROA is headquartered in Auckland, New Zealand and is listed on the Australian Securities Exchange (ASX: ARX). www.aroa.com/

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