

Melodi Matrix™ in Breast Reconstruction

NCT06027996

Status	RECRUITING
Phase	Not Applicable
Sponsor	Melodi Health, Inc.
Enrollment	702 participants

Key Eligibility Criteria

Inclusion (4)

- Female.
- Age 22 or older at the time of enrollment.
- Is scheduled to undergo unilateral or bilateral mastectomy (including prophylactic) with immediate two-stage post-mastectomy alloplastic prepectoral breast reconstruction.
- Is able to and willing to comply with the study requirements and providing informed consent.

Exclusion (11)

- Has prior history of neoadjuvant radiotherapy.
 - Has had prior history of failed tissue expansion or breast implantation at the intended reconstruction site.
 - Has an active abscess or infection requiring antibiotics anywhere in their body within 30 days.
 - Has a Body Mass Index (BMI) < 14 or > 40 .
 - Is pregnant or is nursing; or plans to become pregnant during the course of the study.
- ... and 6 more (see full listing online)

Locations (10 total)

Stanford University, Palo Alto, California, United States
University of Michigan Health, Ann Arbor, Michigan, United States
Mayo Clinic, Rochester, Minnesota, United States
... and 7 more locations