

# Post-marketing Clinical Monitoring of Safety and Performance of Breast Tissue Expander for Breast Reconstruction

NCT06981481

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**Status** RECRUITING  
**Sponsor** Silimed Industria de Implantes Ltda  
**Enrollment** 152 participants

## Key Eligibility Criteria

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### Inclusion (6)

- provide written informed consent
- female sex at birth;
- be 18 years of age or older;
- have an indication for reconstruction with breast expander + breast implant(s);
- have a plan to receive an expander with a textured surface from the Silimed® brand + implant breast with textured surface from the Silimed® brand;

... and 1 more (see full listing online)

### Exclusion (13)

- breast augmentation without reconstruction in at least one breast;
- neoplasia of any type (except breast neoplasia), not yet treated or under treatment, or requiring surgical removal at the time of implantation;
- pregnancy or breastfeeding at the time of implantation;
- smoking, uncontrolled diabetes, obesity (from grade 2) and ASA III/IV;
- active infection not yet treated or being treated at any site at the time of implantation;

... and 8 more (see full listing online)

## Locations (3 total)

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Hospital de câncer HCIII (INCA), Rio de Janeiro, Rio de Janeiro, Brazil  
Fundação do ABC - Centro universitário FMABC, Santo André, São Paulo, Brazil  
Irmandade Santa Casa de Misericórdia de São Paulo, São Paulo, São Paulo, Brazil