

# An Analysis of Adverse Events and Satisfaction Outcomes of Women Who Underwent Primary and Secondary Breast Augmentation Using Silimed® Breast Implants

NCT03356132

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**Status** RECRUITING  
**Sponsor** Silimed Industria de Implantes Ltda  
**Enrollment** 632 participants

## Key Eligibility Criteria

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### Inclusion (6)

- provide written informed consent.
  - female at birth
  - be 18 years of age or older
  - have received breast implant(s) for indication of primary or secondary augmentation until 21 days before (including the visit window)
  - having received a breast implant with a textured surface or a breast implant with a surface coated with Silimed® polyurethane foam
- ... and 1 more (see full listing online)

### Exclusion (11)

- mammary reconstruction in at least one breast or augmentation after previous reconstruction,
  - pregnancy informed or breastfeeding at the inclusion moment,
  - advanced fibrocystic disease at the time of implantation,
  - neoplasia of any type not yet treated or being treated at the time of implantation, infection in activity not yet treated or being treated at any site at the time of implantation,
  - reporting or recording of adverse reactions or intolerance to polyurethane or silicone prior to implantation,
- ... and 6 more (see full listing online)

## Locations (1 total)

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Perfektua Serviços Médicos Ltda, Niterói, Rio de Janeiro, Brazil