

Post-market Surveillance Study to Evaluate the Quality of Life and the Safety and Effectiveness of the TIGR® Matrix After Reconstructive Breast Surgery

NCT06511167

Status RECRUITING
Sponsor AWOgyn
Enrollment 135 participants

Key Eligibility Criteria

Inclusion (6)

- Women with histologically confirmed breast cancer or precancerosis or genetic pre-existing conditions with increased risk of breast cancer or with a family history all with an indication for skin sparing or nipple sparing mastectomy (SSM or NSM); or women with indication of prophylactic operation
 - The health of women must comply with ECOG performance status 0-2
 - The decision for the implementation of the TIGR® Matrix was made before and independently from study enrollment
 - Participant is mentally able to understand the nature, aims, or possible consequences of the clinical investigation
 - Patient information has been handed out and subject signed informed consent
- ... and 1 more (see full listing online)

Exclusion (9)

- Pregnancy or breast-feeding patients
 - Known intolerance to the material, mesh-implants under investigation
 - Metastatic breast cancer (with a life expectancy < 5 years)
 - Medicinal dis-regulated diabetes
 - Inadequate bone marrow function with neutrophil granulocytes < 1500 and blood plates $< 100.000/\mu\text{l}$
- ... and 4 more (see full listing online)

Locations (5 total)

GRN-Klinik Weinheim, Weinheim, Baden-Wurttemberg, Germany
Klinik und Poliklinik für Frauenheilkunde Technische Universität München, München, Bavaria, Germany
Agaplesion Markus Krankenhaus Frankfurt, Frankfurt am Main, Hesse, Germany
... and 2 more locations