

SYNOPSIS CLINICAL INVESTIGATIONS

TITLE

Clinical trial evaluating medical-grade polycaprolactone-PCL breast scaffold implantation with autologous fat grafting for breast implant revision and congenital defect correction surgery

COUNTRY/CURRENT STATUS

Australia/Waiting for approval

PROJECT NUMBER

2021-BRV-004

NUMBER OF PATIENTS

Up to 20

SYNOPSIS

The 2021-BRV-004 clinical trial will be conducted in Brisbane, Australia under the supervision of the principal investigator Prof. Owen Ung. Up to twenty adult patients will be enrolled at Royal Brisbane and Women's Hospital and will be followed up for two years after surgery. The operation involves the insertion of the investigational device, a 3D printed polycaprolactone scaffold, in the mammary region (pre-pectoral plane) in combination with autologous fat grafting (AFG) for breast implant revision and congenital defect correction surgeries. The objective of the study is to demonstrate the safety and clinical performance of the investigational device for large volume soft tissue reconstruction in breast reconstruction in breast implant revision and congenital defect correction surgeries.