

SYNOPSIS CLINICAL INVESTIGATIONS

TITLE

Clinical trial evaluating medical-grade polycaprolactone-PCL Breast Scaffold implantation with autologous fat grafting for Breast Reconstruction (IT).

Studio clinico per la valutazione dell'impianto di uno scaffold in policaprolattone (PCL), usato in combinazione con trasferimento di tessuto adiposo autologo, per la ricostruzione del seno.

COUNTRY/CURRENT STATUS

Italy/Waiting for approval

PROJECT NUMBER

2021-BRC-003

NUMBER OF PATIENTS

10

SYNOPSIS

The 2021-BRC-003 clinical trial will be conducted in Rome, Italy under the supervision of the principal investigator Prof. Fabio Santanelli. Ten adult patients will be enrolled at Sant'Andrea 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 unilateral or bilateral breast reconstruction. Primary breast reconstruction, including women with breast cancer where mastectomy is indicated but adjuvant radiotherapy and/or chemotherapy is not necessary; women with genetic mutation requiring prophylactic mastectomies; women with breast deformities and/or congenital defects will be enrolled. 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 surgeries.