

SYNOPSIS CLINICAL INVESTIGATIONS

TITLE

Clinical trial evaluating medical-grade polycaprolactone-PCL Pectus scaffold implantation with autologous fat grafting for pectus excavatum camouflage.

COUNTRY/CURRENT STATUS

Australia/Active

PROJECT NUMBER

2020-PEC-001

NUMBER OF PATIENTS

10

SYNOPSIS

The 2020-PEC-001 clinical is conducted in Brisbane, Australia under the supervision of the principal investigator Dr. Michael Wagels. Ten adult patients will be enrolled at Princess Alexandra Hospital and will be followed up for two years after surgery. The operation involves the insertion of the investigational device, a custom-made 3D printed polycaprolactone scaffold, in the thorax region in combination with autologous fat grafting (AFG) to camouflage pectus excavatum defects in patients unsuitable for conventional treatment with stable cardio-respiratory function. The objective of the study is to demonstrate the safety and clinical performance of the investigational device for large volume soft tissue reconstruction in pectus excavatum camouflage.