

CONNECT: A Multi-Cohort, Prospective Investigation of the Symani® Surgical System

NCT06866197

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| Status | RECRUITING |
| Phase | Not Applicable |
| Sponsor | MMI (Medical Microinstruments, Inc.) |
| Enrollment | 180 participants |

Key Eligibility Criteria

Inclusion (13)

- Adults, according to the local law
- Patient agrees to participate in the study, return for all required follow-up visits, and has willingly provided written informed consent after receiving all information related to the study, its requirements, and the robotic assisted procedure
- Patient with a clinical indication for a microsurgical anastomosis for a free flap transfer surgery and/or lymphatic surgery
Investigator considers candidate acceptable for free flap transfer surgery and/or lymphatic surgery with a robotic assisted microsurgical anastomosis in accordance with the Symani System IFU
- For lymphedema of the extremities, swelling of lymphedema that is not completely reversed by decongestion therapy modalities. (Not applicable for patients with lymphedema of the head and neck)
- For lymphedema of the extremities, at least one of the following positive quantitative measurements (not applicable for patients with lymphedema of the head and neck):
... and 8 more (see full listing online)

Exclusion (23)

- Patients who are not capable and/or unwilling to provide informed consent
- Clinically significant cardiovascular, digestive, respiratory, endocrine, liver or central nervous system disorders, previous mental disorders, or other disorders that may significantly affect the data collection or the ability to comply with the protocol per the investigators discretion.
- Known history of significant bleeding, coagulopathy, or Von Willebrand's disease
- Patients with implanted pacemaker
- Planned vein graft (either venous or arterial)
... and 18 more (see full listing online)

Locations (1 total)

Saint Vincent's Hospital Melbourne, Melbourne, Victoria, Australia