

Transtibial Osseointegration

NCT06636136

Status	RECRUITING
Phase	Not Applicable
Sponsor	Walter Reed National Military Medical Center
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (13)

- Diagnosis of a transtibial amputation age 22-65.
- The OPRA™ Implant System is indicated for patients who have transtibial amputation due to trauma or cancer and who have or are anticipated to have rehabilitation problems with, or cannot use, a conventional socket prosthesis. The OPRA™ Implant System is intended for skeletally mature patients.
- The patient failed to receive benefit from socket prostheses or is expected to not tolerate socket use due to problems such as:
- Recurrent skin infections and ulcerations in the socket contact area
- Pain

... and 8 more (see full listing online)

Exclusion (19)

- The patient's skeletal growth is not complete. Completed skeletal growth is defined through the finding of generally closed epiphyseal zones on X-ray.
- The patient has atypical skeletal anatomy which may affect treatment with OPRA™.
- Examples of atypical skeletal anatomy.
- Skeletal dimensions outside defined interval.
- Development anomalies.

... and 14 more (see full listing online)

Locations (2 total)

Orthopaedic Surgery Service, Walter Reed National Military Medical Center, Bethesda, Maryland, United States
Department of Orthopaedic Surgery and Department of Anesthesiology & Critical Care Penn Medicine University City, Philadelphia, Pennsylvania, United States