

# TrueLok Elevate PMCF Study

NCT07079774

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**Status** RECRUITING  
**Sponsor** Orthofix s.r.l.  
**Enrollment** 153 participants

## Key Eligibility Criteria

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### Inclusion (4)

- Aged 18 years or older at the time of surgery Willing and able to sign and date the study-specific informed consent form in accordance with national and institutional ethics requirements Willing and able to comply with requirements of the protocol, including follow-up requirements Indicated for surgical intervention using the TrueLok Elevate Transverse Bone Transport System for the treatment of soft tissue defects in the form of lower limb ulcers
- Presence of a chronic ulcer, defined as:
  - Present for at least 3 months, and
  - Unresponsive to standard non-surgical or surgical wound management, including but not limited to debridement, negative pressure wound therapy (VAC), offloading, antibiotics, or vascular optimisation

### Exclusion (8)

- Mental or cognitive impairment or physiological or behavioural conditions that, in the opinion of the investigator, would preclude reliable adherence to postoperative care instructions, follow-up assessments, or study procedures
- Known or presenting with the following signs of a systemic inflammatory response syndrome (SIRS) as exhibiting two or more of the following conditions:
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  - Heart rate  $\gt 90$  beats/min
  - Respiratory rate  $\gt 20$  breaths/min... and 3 more (see full listing online)

## Locations (5 total)

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Helios Klinikum Wuppertal GmbH, Wuppertal, Germany  
General Regional Hospital F. Miulli of Acquaviva delle Fonti, Acquaviva delle Fonti, Bari, Italy  
Stellenbosch University, Cape Town, Western Cape, South Africa  
... and 2 more locations