

# Post-market Clinical Follow-up (PMCF) Study of the Poly-Tape Devices for Medial Patellofemoral Ligament (MPFL) Reconstruction

NCT05264389

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**Status** RECRUITING  
**Sponsor** Xiros Ltd  
**Enrollment** 59 participants

## Key Eligibility Criteria

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### Inclusion (1)

- Patient must be 13 years old or above. Patients who require MPFL reconstruction. Patients willing to participate in the study and have been informed of the nature of the study, agree to its follow-up and have provided written informed consent as approved by the Research Ethics Committee (REC).

### Exclusion (5)

- These devices should not be used in procedures which bridge, disturb, or disrupt the growth plate in immature patients since they will not elongate as the patient grows.
- Patients known to be hypersensitive to titanium alloy or polyester. Appropriate tests should be carried out on patients with suspected material sensitivity prior to implantation.
- Patients with any infections or structural or pathological condition of the bone or soft tissue that would be expected to impair healing or secure fixation. Bone quality should be assessed prior to surgery.
- Patients who are unable or unwilling to restrict activities to prescribed levels or to follow the rehabilitation instructions during the healing period.
- Patients for whom the implantation is intended to be non-permanent, since they integrate well with the patient's tissue.

## Locations (5 total)

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James Paget University Hospitals NHS Foundation Trust, Great Yarmouth, United Kingdom  
Tameside and Glossop Integrated Care NHS Foundation Trust, Manchester, United Kingdom  
University of North Midlands NHS Trust, Stoke-on-Trent, United Kingdom  
... and 2 more locations