

PMCF (Post-Market Clinical Follow-up) Study on The Tether™ in UK (United Kingdom)

NCT05830825

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| Status | RECRUITING |
| Sponsor | LDR Médical SAS |
| Enrollment | 100 participants |

Key Eligibility Criteria

Inclusion (8)

- Diagnosis of progressive idiopathic scoliosis;
- Skeletally immature, based on both Risser (<5) and Sanders (<8) assessments;
- Major Cobb angle $\geq 30^\circ$ and $\geq 65^\circ$;
- Osseous structure dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging;
- Failed bracing and/or be intolerant to brace wear;
- ... and 3 more (see full listing online)

Exclusion (7)

- Presence of any systemic infection, local infection, or skin compromise at the surgical site;
- Prior spinal surgery at the level(s) to be treated;
- Known poor bone quality defined as a T-score ≤ -1.5 or less;
- Skeletal maturity;
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as coagulation disorders, allergies to the implant materials, and patients unwillingness or inability to cooperate with post-operative care instructions;
- ... and 2 more (see full listing online)

Locations (3 total)

Saint George's Hospital, London, United Kingdom
Freeman Hospital, Newcastle upon Tyne, United Kingdom
University Southampton Hospital, Southampton, United Kingdom