REFLECT Scoliosis System Post Approval Study

NCT06298812

Status	RECRUITING
Phase	Not Applicable
Sponsor	Globus Medical Inc
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (7)

- Diagnosis of progressive idiopathic scoliosis
- Preoperative major Cobb angle 30°-65°
- Preoperative flexibility to d30° on side bending radiograph (left or right)
- Skeletally immature at the time of surgery with Risser sign \<5 or Sanders score \<8
- Osseous structure dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging

... and 2 more (see full listing online)

Exclusion (6)

- Prior spinal surgery at the level(s) to be treated
- Documented poor bone quality, defined as a T-score of -1.5 or less
- Presence of any systemic infection, local infection, or skin compromise at the surgical site
- Any medical or surgical condition which would preclude the potential benefit of spinal surgery, such as coagulation disorders, allergies to the implant materials, and patient's unwillingness or inability to cooperate with post-operative care instructions
- Unwillingness, inability, or living situation (e.g. custody arrangements, homelessness, detention) that would preclude ability to return to the study site for follow-up visits as described in protocol and Informed Consent

... and 1 more (see full listing online)

Locations (2 total)

Mayo Clinic, Rochester, Minnesota, United States
New York University, New York, New York, United States