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Long-term results after back surgery for deformity using the Romeo®2 System

Submission date
14/01/2026

Recruitment status
Not yet recruiting

Registration date
15/01/2026

Overall study status
Ongoing

Last Edited
27/01/2026

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims:
Posterior screw fixation is a well-known surgical method used to stabilize the middle and lower parts of the spine when there are problems like spinal deformities. The Romeo® 2 and Romeo® 2 MIS systems are recognized and widely used technologies for this purpose. The aim of the study is to gather and review real-world evidence over time to confirm that these systems are effective, safe and provide clinical benefits for treating spinal deformities.

Who can participate?
This study involves only the collection and analysis of existing data. We will include data from patients in the participating centers who previously underwent surgery using the ROMEO®2 or ROMEO®2 MIS system to treat spinal deformity, provided that images and questionnaire results are available from at least 22 months after surgery. Data will only be used if the patient has not formally objected to its use for research purposes.

What does the study involve?
All the data will be collected per the sites' standard of care and based on their availability in the medical records as real-world evidence. This includes preoperative data, surgical details, and immediate to long-term postoperative follow-up information.

What are the possible benefits and risks of participating?
As this is a retrospective data collection study, there are no direct benefits or risks for participants. The study uses only existing data, and no additional procedures or interventions will be performed.

Where is the study run from?
Spineart SA (Switzerland)

When is the study starting and how long is it expected to run for?
March 2026 to August 2026

Who is funding the study?
Spineart SA (Switzerland)

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Internal reference
P50_CLD002

Study information

Scientific Title
Evaluation of long-term clinical and radiographic outcomes after spinal surgery using the Romeo®2 / Romeo®2 MIS posterior fixation system to treat spinal deformities

Acronym
Romeo®2 Deformity

Study objectives
To confirm over time the clinical benefit, the performance and the safety of the Romeo®2 / Romeo®2 MIS system.

Ethics approval required
Ethics approval not required

Ethics approval(s)

Primary study design
Observational

Secondary study design
Case series

Study type(s)

Health condition(s) or problem(s) studied
Chronic instabilities or deformities of the thoracic, lumbar and sacral spine due to degenerative disc disease (painful degeneration of the disc), spondylolisthesis, spinal stenosis (up to 4 levels), tumor (1 level), trauma (up to 2 levels), deformities (i.e. scoliosis, kyphosis, or lordosis) indicated up to 15 levels

Interventions
Current methodology as of 27/01/2026:
The study is observational, only a retrospective collection of existing data is planned.
As the primary function, the ROMEO® 2 System is intended to provide immobilization and stabilization of spinal segments for the treatment of thoracolumbar spine instabilities due to spinal deformities.
The study aims to confirm over time the clinical benefit of the ROMEO®2 / ROMEO®2 MIS system by assessing patient-reported outcomes when available, including pain using the Visual Analog Scale (VAS) for back and leg, functional capacity using the Oswestry Disability Index (ODI), and health-related quality of life using the SRS-22r questionnaire. It also seeks to confirm the system’s performance by evaluating the deformity correction on EOS or full-spine X-rays (when images are available) and the posterior fusion status at last follow up visit. The study also serves to confirm the long-term safety of ROMEO®2 / ROMEO®2 MIS system.

Previous methodology:
The study is observational, only a retrospective collection of existing data is planned.
As the primary function, the ROMEO® 2 System is intended to provide immobilization and stabilization of spinal segments for the treatment of thoracolumbar spine instabilities due to spinal deformities.
The study aims to confirm over time the clinical benefit of the ROMEO®2 / ROMEO®2 MIS system by assessing patient-reported outcomes when available, including pain using the Visual Analog Scale (VAS) for back and leg, functional capacity using the Oswestry Disability Index (ODI), and health-related quality of life using the SRS-22r questionnaire. It also seeks to confirm the system’s performance by evaluating deformity correction on EOS or full-spine X-rays when images are available, and to confirm its long-term safety.

Intervention Type

Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Romeo®2 / Romeo®2 MIS system

Primary outcome(s)
1. Pain (back and leg) measured using visual analogue scale (VAS) at the last postoperative follow-up visit and at each postoperative follow-up visit versus baseline (if data available)

2. Functional capacity measured using Oswestry Disability Index (ODI) at the last postoperative follow-up visit and at each postoperative follow-up visit versus baseline (if data available)

3. Health-related quality of life measured using SRS-22r at the last postoperative follow-up visit and at each postoperative follow-up visit versus baseline (if data available)

Updated 27/01/2026, previous primary outcomes:
1. Pain (back and leg) measured using visual analogue scale (VAS) at each postoperative follow-up visit versus baseline (if data available)
2. Functional capacity measured using Oswestry Disability Index (ODI) at each postoperative follow-up visit versus baseline (if data available)
3. Health-related quality of life measured using SRS-22r at each postoperative follow-up visit versus baseline (if data available)

Key secondary outcome(s))
1. Correction and maintenance of the deformity measured using spinopelvic parameters in the coronal plane (Cobb angle, coronal balance (C7 plumb line), lumbar spine modifier) at each postoperative follow-up visit versus baseline

2. Correction and maintenance of the deformity measured using spinopelvic parameters in the sagittal plane (lumbar lordosis, thoracic kyphosis T1-T12 & T5-T12 angles, pelvic incidence, sacral slope, pelvic tilt, sagittal vertebral axis, C7 slope, odontoid to hip axis angle, PI-LL mismatch) at each postoperative follow-up visit versus baseline

3. Posterior fusion status measured using visual assessment at last postoperative follow-up visit

4. Fusion status (in case of interbody device implantation) measured using Brantigan-Steffee-Fraser (BSF) classification at last postoperative follow-up visit

5. Safety measured using reported adverse device effects (ADEs), serious adverse device effects (SADEs), Unanticipated Serious Adverse Device Effects (USADEs) including all surgical revisions and reoperations at all the postoperative follow-up visits and during surgery (if data available)

6. Safety measured using the rate of device deficiencies that might have led to a SADE at all the postoperative follow-up visits (if data available)

Updated 27/01/2026, previous secondary outcomes:
1. The correction of the deformity and its maintenance measured using spinopelvic parameters in the coronal plane (Cobb angle, coronal balance (C7 plumb line), lumbar spine modifier) at each

postoperative follow-up visit versus baseline
2. The correction of the deformity and its maintenance measured using spinopelvic parameters in the sagittal plane (lumbar lordosis, thoracic kyphosis T1-T12 & T5-T12 angles, pelvic incidence, sacral slope, pelvic tilt, sagittal vertebral axis, C7 slope, odontoid to hip axis angle, PI-LL mismatch) at each postoperative follow-up visit versus baseline
3. The fusion status (in case of interbody device implantation) measured using Brantigan-Steffee-Fraser (BSF) classification at last postoperative follow-up visit
4. Safety measured using reported adverse device effects (ADEs), serious adverse device effects (SADEs), Unanticipated Serious Adverse Device Effects (USADEs) including all surgical revisions and reoperations at all the postoperative follow-up visits and during surgery (if data available)
5. Safety measured using the rate of device deficiencies that might have led to a SADE at all the postoperative follow-up visits (if data available)

Completion date
31/08/2026

Eligibility

Key inclusion criteria
1. Patients who have received Romeo®2 / Romeo®2 MIS system for spinal deformities
2. Patients with questionnaires at 22 months or more after surgery with Romeo®2 / Romeo®2 MIS system

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Written opposition by the patients and if applicable their legal representative (for minors) for their data collection for this study

Date of first enrolment
01/03/2026

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
France

Study participating centre
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POITIERS

Study participating centre
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2 Allée Dr Robert Lafon
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Sponsor information

Organisation
Spineart (Switzerland)

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type

Funder Name
Spineart SA

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available