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Evaluation of the performance and safety of the SCARLET® AC-Ti interbody cage after surgery of the cervical spine

Submission date
02/06/2026

Recruitment status
Not yet recruiting

Registration date
03/06/2026

Overall study status
Ongoing

Last Edited
03/06/2026

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
Degenerative conditions of the cervical spine (neck), such as degenerative disc disease and spondylosis, can cause neck pain, arm pain and nerve problems. When non-surgical treatments are no longer effective, a common treatment is anterior cervical discectomy and fusion (ACDF), where the damaged disc is removed and the bones are stabilised to allow them to fuse together. The SCARLET® AC-Ti device is an implant already used in routine clinical practice for this type of surgery. This study aims to evaluate how well this device works and how safe it is in real-life conditions, particularly by assessing whether the bones successfully fuse after surgery and how patients recover over time.

Who can participate?
Adults aged 18 years and older who are scheduled to undergo cervical spine surgery using the SCARLET® AC-Ti device

What does the study involve?
The study involves collecting information before surgery, during the hospital stay, and at followup visits between 4 and 12 weeks, and then at around 6, 12 and 24 months after surgery, including medical assessments, imaging (such as Xrays and CT scans), and questionnaires about recovery (arm and neck pain, Neck Disability Index).

What are the possible benefits and risks of participating?
Participants will receive the same surgery whether or not they take part, and any potential benefits are related to the standard treatment and not related to their participation in the study. The risks of surgery are those normally expected for this procedure and are not increased by participation. Additional visits and questionnaires do not pose any risk to participants. However, compared to standard practice at each site, participation may involve additional imaging, which may slightly increase exposure to ionising radiation.

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

When is the study starting and how long is it expected to run for?
October 2026 to October 2029

Who is funding the study?
Spineart SA (Switzerland)

Who is the main contact?
clinic@spineart.com

Contact information

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Scientific, Public

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Additional identifiers

Study information

Scientific Title
Prospective evaluation of clinical and radiographic outcomes following anterior cervical interbody fusion surgery using the SCARLET® AC-Ti cage

Acronym
P94_CLD001

Study objectives
The primary objective of this study is to confirm the clinical performance of the SCARLET® AC-Ti cervical interbody cage in patients undergoing anterior cervical discectomy and fusion (ACDF), by assessing the fusion rate at the treated level(s).

The secondary objectives are to further evaluate device performance through radiographic outcomes (such as spinal alignment, stability, subsidence and adjacent segment degeneration) and to assess clinical benefits including neurological outcomes, pain, functional status and patient satisfaction following surgery.

The safety objective is to assess the safety of the SCARLET® AC-Ti device and its instrumentation throughout the study by monitoring adverse events and any surgical reinterventions.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Cervical radiculopathy and/or myelopathy, secondary to degenerative disc disease (DDD) and/or spondylosis at consecutive levels between C3 and C7

Interventions
Anterior Cervical Discectomy and Fusion (ACDF) technique treatment. The goal of anterior cervical interbody cages used in ACDF surgical procedures is to obtain a solid union between two or more vertebrae. The solid fusion usually occurs between 6 and 12 months and up to 24

months. Over 24 months, it is generally considered that the fusion failed. The procedure with the SCARLET AC-Ti cage may not involve the use of supplemental instrumentation such as anterior cervical plates.
Once eligibility criteria are met and the patient agrees to participate by signing an informed consent, data will be collected for the following visits: preoperative visit, surgery, hospital discharge, 4-12 weeks postoperative visit, 6 months (+/- 1 month) postoperative visit, 12 months (+/-2 months) postoperative visit, and 24 months (+/-2 months) postoperative visit.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
SCARLET® AC-Ti

Primary outcome(s)
1. Fusion rate at the treated level(s) by the presence of a continuous bone bridge outside the cage, without a transverse lucent line crossing the peripheral margins of the operated disc space, measured using computed tomography (CT) scan at 6 months and repeated at 12 and 24 months post-surgery if the previous CT scan did not show a solid fusion

Key secondary outcome(s))
1. Fusion rate (no level fused/at least one level fused/all levels fused) measured using computed tomography (CT) scan at 6 months and within 24 months

2. Fusion time (time to fusion in months) measured using computed tomography (CT) scan at 6 months and within 24 months

3. Performance of SCARLET® AC-Ti measured using neutral lateral X-rays of the cervical spine at 4-12 weeks, 6, 12 and 24 months postoperatively, by means of the Cobb angle compared to the preoperative visit

4. Sagital vertical axis (SVA) measured using neutral lateral X-rays at 4-12 weeks, 6, 12 and 24 months postoperative visits compared to the preoperative visit

5. Subsidence incidence of the operated segments measured using neutral lateral X-rays at the 4-12 weeks, 6, 12 and 24 months postoperative visits

6. Adjacent segment disease (ASD) rate measured using neutral lateral X-rays at 6, 12 and 24 months

7. Clinical benefit measured using clinical and neurological examinations and patient-reported outcomes (visual analogue scale [VAS] arm and neck pain and Neck Disability Index [NDI] scores) at 4-12 weeks, 6, 12, and 24 months postoperatively compared to the preoperative visit, in addition to patient’s satisfaction at 12 and 24 months postoperatively

8. SCARLET® AC-Ti surgical instrumentation performance and safety according to its intended use measured using surgeons’ reporting at each surgical step (preparation of the implantation site, selection, insertion, manipulation, and adjustment of the implant)

9. Safety of the SCARLET® AC-Ti measured using the incidence, seriousness, severity, action taken, outcome and timing of all adverse device effects (ADEs), serious adverse device effects (SADEs), and unanticipated serious adverse device effects (USADEs), as well as all surgical revisions, re-operations, and other unrelated operations and the rate of device deficiencies that might have led to a SADE, at surgery and within the 24-month postoperative follow-up period

Completion date
31/10/2029

Eligibility

Key inclusion criteria
1. Patients who are scheduled for a surgery with at least one SCARLET® AC-Ti cage
2. Patients willing and able to comply with follow-up schedule, imaging exams and questionnaires completion
3. Written voluntary informed consent signed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients under 18 years of age
2. Patients whose cervical/radicular pain could be attributable to a diagnosis other than cervical disc degenerative disease (DDD) and/or spondylosis or who have a contraindication listed in the device IFU
3. Patients who are unlikely to comply with the 24-month follow-up schedule due to medical, cognitive, social, or logistical reasons

Date of first enrolment
19/10/2026

Date of final enrolment
19/10/2027

Locations

Countries of recruitment
United Kingdom

England

Belgium

France

Study participating centre
Northumbria Healthcare NHS Foundation Trust
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Study participating centre
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Sponsor information

Organisation
Spineart (Switzerland)

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type

Funder Name
Spineart (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available