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Evaluation of outcomes after spinal fusion with a Scarlet® ALT Hyperlordotic titanium secured cage implant

Submission date 27/09/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2023	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 07/03/2025	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Degenerative Disc Disease (DDD) is a condition where the discs that separate and cushion the vertebrae in the spine break down and lose their ability to absorb shock. This can cause pain, stiffness, and reduced mobility in the back or neck.
Anterior lumbar interbody fusion (ALIF) with cages is a surgical procedure used to treat certain conditions of the lower back, such as degenerative disc disease, herniated discs, or spinal instability. During the procedure, the surgeon makes an incision in the front of the abdomen, and the affected disc is removed from between the vertebrae. A cage made of bone, metal, or plastic is then inserted into the space left by the removed disc. The cage is packed with bone graft material, which over time grows and fuses the adjacent vertebrae together, stabilizing the spine. The use of cages in ALIF procedures has been a well-established technology for several decades and has been found to be effective in treating certain conditions of the lower back. Recently, cages with integrated fixation have been used to make the devices safer and more effective in promoting fusion. SCARLET® AL-T Hyperlordotic cage (≥20°) is a device that was introduced in 2021 and is categorized as a secured lumbar anterior cage. It should be used with integrated fixation by the mean of the bone screws provided and also an additional supplemental fixation system that has been cleared for use in the lumbosacral spine. It has been shown that this type of device is effective in treating Degenerative Disk Disease. The aim of this study is to collect real-world evidence on the safety and clinical benefits of SCARLET® AL-T Hyperlordotic for around 20 months after surgery. The goal is to confirm that the SCARLET® AL-T system Hyperlordotic is safe and effective for long-term clinical benefits and radiographic outcomes after ALIF surgery.

Who can participate?
Patients at least 18 years old needing ALIF surgery for DDD who received the SCARLET®AL-T Hyperlordotic system

What does the study involve?
The pre-operative data, surgical data, and discharge data will be collected retrospectively, and the postoperative data at <4 months, 4-9 months, and 9-20 months will be collected either

retrospectively or prospectively, and the >20 months post-operative data will be collected prospectively.
CT scans will be performed over time as per standard of care, except at the last prospective FU (V7) where it is compulsory.
Patient questionnaires will be completed by patients to collect clinical data and evaluate changes in pain, disability and improvement between baseline and post-operation as per standard of care.

What are the possible benefits and risks of participating?
There are no anticipated benefits for the patients participating in the study. There are no potential risks for the retrospective part for the patients participating in the study, as the study is a collection of real-world evidence data based on the site standard of care. The last postoperative visit is prospective and a CT scan will be performed. Depending on the site, the CT scan may be part of the site standard of care or an additional radiographic exam for the patient. In the case the CT scan is in addition to the site standard of care and the ionization risk is slightly increased.

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

When is the study starting and how long is it expected to run for?
May 2023 to December 2025

Who is funding the study?
Spineart SA (Switzerland)

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
P76_CLD002

Study information

Scientific Title
Clinical and radiological evaluation after anterior lumbar interbody fusion surgery with Scarlet ALT Hyperlordotic

Acronym
Scarlet® AL-T Hyperlordotic

Study objectives
The SCARLET®AL-T Hyperlordotic system is a class IIb (under MDD) CE-marked device since January 2021. It is a lumbar anterior intersomatic cage intended to perform fusion between lumbar vertebrae after discectomy. The clinical and radiographic outcomes evaluation should confirm the performance and safety of the cage.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/08/2023, CPP Sud Est II (Groupement hospitalier Est - Bâtiment Pinel - 59, Boulevard Pinel, Bron, 69500, France; +33 (0)4 27 85 62 46; cpp.sud-est-2@chu-lyon.fr), ref: 2023-A01176-39

Study design
Multicentric single-arm post-market clinical follow-up study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Surgical treatment of Degenerative Disk Diseases (DDD) of the lumbar spine at various contiguous level from L2 to S1

Interventions
The SCARLET®AL-T system is implanted via an open or a minimally invasive anterior approach (ALIF).

All the data will be collected per the sites' standard of care and based on their availability as real-world evidence for the retrospective visits. The last postoperative visit is mandatory as well as a CT scan to measure fusion.

Once the patient agrees to participate, the informed consent form is completed and eligibility criteria have been confirmed, the following data are collected:
1. Fully retrospective visits: preoperative visit (V1), surgery (V2), and discharge (V3).
2. Depending on the inclusion date - retrospective or prospective visits: 1st FU visit <4 months post-operation (V4), between 4-9 months PO (V5), between 9-20 months PO (V6)
3. Fully prospective visit: Last FU visit >20 months PO (V7)

Total duration of observation: around 25 months depending when will be done the inclusion

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)
SCARLET®AL-T Hyperlordotic system

Primary outcome measure
Interbody fusion rate of the treated level(s), evaluated on radiological images by the surgeon within the study FU period as Solid fusion, Fibrous union, or Non-union. The performance of Scarlet® AL-T Hyperlordotic will be demonstrated if >90% of the patients have a "solid fusion" acquired within the study on all level(s) treated with Scarlet® AL-T Hyperlordotic evaluated on radiological images at <4 months (V4), 4-9 months (V5), 9-20 months (V6), and >20 months (V7) PO.

Secondary outcome measures
The performance of Scarlet® AL-T Hyperlordotic will be measured or confirmed by:
1. The time to fusion (in months) of the treated level (s) based on the fusion status (solid fusion confirmed) on radiological images at <4 months (V4), 4-9 months (V5), 9-20 months (V6) and >20 months (V7)
2. The lumbar lordosis restoration on radiological images, by measuring the Cobb angle (°) between the superior sacral plate and the superior surface of the L-1 vertebra, at discharge (V3) and <4 months (V4), 4-9 months (V5), 9-20 months (V6), >20 months (V7) postoperation (PO), compared to the preoperative visit.
3. The sagittal balance (positive, neutral or negative) restoration on radiological images, by

measuring the C7 plumb line, at discharge (V3) and <4 months (V4), 4-9 months (V5), 9-20 months (V6), >20 months (V7) PO, compared to the preoperative visit
4. The clinical benefit, by assessing low back disability and change in disability using the Oswestry Disability Index (ODI) questionnaire at <4 months (V4), 4-9 months (V5), 9-20 months (V6), and >20 months (V7) PO compared to preop (V1)
5. The patient's pain (back and leg) using the Visual Analogue Scale (VAS) at <4 months (V4), 4-9 months (V5), 9-20 months (V6), and >20 months (V7) PO compared to preop (V1)
5. The clinical benefit with the clinical and neurological examination (low back pain, motor /sensory deficit) assessed by the surgeon at discharge (V3), and <4 months (V4), 4-9 months (V5), 9-20 months (V6), and >20 months (V7) PO compared to the preoperative visit.
6. The safety by assessing the subsidence rate and type (early or delayed and cranial or caudal) assessed on radiological images at treated level(s) at <4 months (V4), 4-9 months (V5), 9-20 months (V6), >20 months (V7) PO.
7. The safety by assessing the osteolysis rate around Scarlet® AL-T Hyperlordotic and its screws, assessed on radiological images as lucency at the cage margins or around screws, at <4 months (V4), 4-9 months (V5), 9-20 months (V6), >20 months (V7) PO. A lucency suggests device movement at the operated level and loosening of the device.
8. The Scarlet® AL-T Hyperlordotic safety throughout the study to the last post-operative FU by reporting the incidence and time to resolution of all adverse device effects (ADEs) and all serious adverse events (SAEs) including all surgical revisions.

Overall study start date
17/05/2023

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Patients who received at least one Scarlet® AL-T Hyperlordotic
3. Informed Consent Form signed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. Subject who had been deprived of their freedom by administrative or legal decision or who is under guardianship
2. Subject who does not speak/understand French

Date of first enrolment
28/09/2023

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
France

Study participating centre
Hôpital privé le Bois
44 avenue Marx Dormoy
Lille
France
59000

Study participating centre
CCV Montpellier
Clinique du Parc
50 rue Emiles Combes
Castelnau Le Lez
France
34170

Study participating centre
CHU Pellegrin
Place Amélie Raba Léon
Bordeaux
France
33076

Sponsor information

Organisation
Spineart (Switzerland)

Sponsor details
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Sponsor type
Industry

Website
https://www.spineart.com/

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type
Industry

Funder Name
Spineart SA

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional documents can be obtained upon request from clinic@spineart.com.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The dataset generated and analysed during the current study will be available upon request from clinic@spineart.com.
The type of data that will be shared: clinical data of the study
Dates of availability: up to 2040
Participants will be required to provide consent.
All subjects' data are pseudo-anonymized
There are no ethical or legal restrictions.

IPD sharing plan summary

Available on request