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Evaluating outcomes after cervical surgery using a SCARLET® AC-T, Tryptik® CA/CC, or Tryptik® MC cervical interbody cage

Submission date 09/10/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/10/2024	**Overall study status** Ongoing	
Last Edited 10/03/2026	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

Anterior cervical discectomy fusion (ACDF) surgery has become a standard treatment for cervical disc disease, and it is a proven intervention for patients with myelopathy and radiculopathy as it affords the surgeon the ability to provide direct (from the discectomy) and indirect (through the restoration of disc height) decompression and stabilization. Various implant and graft devices have been developed for use with ACDF. The principal pathologies and indications are degenerative disc disease (DDD) referred to as age-related wear and tear of the intervertebral disks, spondylosis, radiculopathy and/or myelopathy secondary to spondylosis, and instability /trauma. The SCARLET® AC-T, Tryptik® CA/CC, and Tryptik® MC devices are legacy devices approved on the market for several years, 2005 for Tryptik® CA/CC and Tryptik® MC, and 2013 for SCARLET® AC-T, for ACDF surgery. As a primary function, they are intended to stabilize the spinal segment to promote fusion and restrict motion. Today, the three devices are class III CE-marked medical devices under the MDR 2017/745 with similar intended purposes. The three devices have acceptable benefit/risk profiles for their intended use according to current knowledge, SOTA, and post-market surveillance (PMS). This prospective, interventional, triple-arm (the 3 arms of the study are “device” arms), multicentric joint, post-market study will provide long-term clinical evidence to confirm the clinical performance and safety of SCARLET® AC-T, Tryptik® CA/CC, and Tryptik® MC as part of the continuous PMS implemented by Spineart and requested by the EU MDR.

Who can participate?

Patients of at least 18 years of age who have received at least one and up to 2 SCARLET® AC-T consecutive cages between C3 and C7 levels, or at least one and up to 3 TRYPTIK® CA/CC cages between C3 and C7 levels, or at least one and up to 3 TRYPTIK® MC cages between C3 and C7 levels.

What does the study involve?

The study is on three groups of patients having ACDF surgery with one of the investigated devices SCARLET® AC-T, Tryptik® CA/CC, or Tryptik® MC. The choice of the device is not randomly assigned. Each site/surgeon uses only one device per their standard practices. Pre-

operative data (V1), surgical data (V2) and discharge data (V3), post-operative data at 4-6 weeks (V4), 12 months +/4 weeks (V5) and 24 +/4 weeks (V6) will be prospectively collected. This includes lateral X-rays (subsidence, ASD) at 4-6 weeks (V4), 12 (V5) and 24 (V6) months Post-operatively, and CT scans (Fusion) at 12 (V5) and 24 (V6) months Post-operatively. Patient questionnaires will be completed by patients to evaluate changes in pain (VAS), and disability (NDI) between baseline and post-operative visits.

What are the possible benefits and risks of participating?
There are no anticipated benefits for the patients participating in the study. The surgery benefit will be the same whether the patients participate in the study or not. Additional visits and questionnaires without risk to the patient. Depending on the sites' standard of care, there is a slight increase in potential risks. If the CT scan to assess the solid fusion rate assessment is performed out of the site standard of care, 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 2024 until December 2027

Who is funding the study?
Spineart SA (Switzerland)

Who is the main contact?
clinic@spineart.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
ACDF_PMC_CLD001

Study information

Scientific Title

Evaluation of clinical and radiographic outcomes after ACDF surgery using a SCARLET® AC-T, Tryptik® CA/CC, or Tryptik® MC interbody cage

Study objectives
The anterior cervical discectomy with fusion (ACDF) treatment using cervical interbody cages is indicated for radiculopathy and/or myelopathy, secondary to cervical degenerative disc disease and/or spondylosis. The Tryptik® CA/CC interbody cage is also indicated for instability (discal or vertebral) as, for example, the result of trauma. The goal of anterior cervical interbody cages used in the ACDF procedure is to obtain a solid union between two or more vertebrae. Fusion may or may not involve the use of supplemental instrumentation such as plates, screws and cages.

This study aims to demonstrate that the legacy devices Tryptik® CA/CC, Tryptik® MC (approved on the market since 2005), and SCARLET® AC-T (approved on the market since 2013) are as performant and safe compared to performance data published for similar other currently marketed systems and that they benefit from an acceptable benefit/risk profile for its intended anterior cervical discectomy with fusion (ACDF) treatment use, according to current knowledge, SOTA, and Post-Market Surveillance (PMS). Due to the low number of subjects in our previous studies, a clinical investigation to conclusively justify the long-term clinical performance, clinical benefits and safety of each device is necessary.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/09/2024, Committee for the Protection of South Mediterranean Persons III (Comité de protection des personnes Sud-Méditerranée III) (UFR Medecine 186 Chemin du Carreau de Lanes, Nîmes, 30900, France; +33 04.66.23.64.33; cppsudmed3@chu-nimes.fr), ref: 2024-A01270-47

Primary study design
Interventional

Study design
Prospective interventional triple-arm multicentric post-market clinical cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-marketing surveillance of interbody cages used for anterior cervical discectomy with fusion (ACDF) treatment

Interventions
The goal of anterior cervical interbody cages used in anterior cervical discectomy with fusion (ACDF) surgical procedures is to obtain a solid union between two or more vertebrae. The solid fusion usually occurs between 6 to 12 months and up to 24 months. Over 24 months, it is generally considered that the fusion failed.

SCARLET® AC-T can be used in up to 2 consecutive levels. Tryptik® CA/CC and Tryptik® MC can be used in up to 3 consecutive levels. These devices are MDR CE certified and class III CE marked medical devices.

The fusion rate will be assessed by CT scan images. Bone scintigraphy may be performed only to confirm the fusion status in case of pseudoarthrosis.

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 (V1); surgery (V2); imm post op/discharge (V3); 4-6 weeks post-op (V4); 12 months post- op (V5); 24 months post-op (V6).
Total duration of observation: around 25 months depending on the date of the inclusion.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
SCARLET® AC-T, Tryptik® CA/CC, Tryptik® MC

Primary outcome(s)
Fusion rate at the treated level and at the patient level post-operatively measured qualitatively on CT scans at 12 months post-operative and 24 months if the previous CT scan did not show a solid fusion at the treated level(s). In the case of pseudoarthrosis, bone scintigraphy may be performed at 12 or 24 months to confirm the fusion status, per the sites' standard of care.

Key secondary outcome(s)
1. Performance of the SCARLET® AC-T, Tryptik® CA/CC, and Tryptik® MC cages will be measured using the following:
1.1 The subsidence incidence at the treated levels on lateral cervical X-ray images at V4 (4-6 weeks PO), V5 (12M PO) and V6 (24M PO)
1.2 Adjacent segment disease (ASD) rate during the post-operative FU and the ASD requiring surgery rate
2. The clinical benefits of SCARLET® AC-T, Tryptik® CA/CC, and Tryptik® MC cages will be measured using the following:
2.1 A clinical and neurological assessment at the preoperative visit (V1), V3 (imm PO) and V4 (4-16 weeks), V5 (12M PO) and V6 (24M PO)
2.2 Patient Reported Outcomes (PRO):
2.2.1. Pain measured using the Visual Analog Scale (VAS arm and neck) self-reported questionnaire at the preoperative visit (V1), V4 (4-16 weeks PO), V5 (12M PO) and V6 (24M PO)
2.2.2. Functional capacity measured using the Neck Disability Index (NDI) self-reported questionnaire at the preoperative visit (V1), V4 (4-16 weeks PO), V5 (12M PO) and V6 (24M PO)
2.2.3. Patient satisfaction measured using a Patient Reported Outcome (PRO) questionnaire scaling from very satisfied to very unsatisfied at V5 (12M PO) and V6 (24M PO)
3. Safety of SCARLET® AC-T, Tryptik® CA/CC, and Tryptik® MC will be measured using the following:
3.1. The incidence and time to resolution of all ADEs (Adverse Device Effects), SADEs (Serious Adverse Device Effects), and USADEs (Unanticipated Serious Adverse Device Effects) including all surgical revisions measured using patient medical records throughout the study to the last

Post-op follow-up
3.2. The rate of device deficiencies measured using patient medical records that might have led to a SADE
4. Performance and safety of SCARLET® AC-T, Tryptik® CA/CC, and Tryptik® MC's instrumentation supporting the surgery measured using data reported in the Case Report Form at one timepoint. The surgeon needs to report four types of performance and safety issues when performing the surgery (preparation of implementation site, implant selection, implant insertion, and finalization of the surgery).
5. Supplemental fixation (as applicable) implanted during the surgery measured using patient medical records

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Patients who are scheduled for surgery:
1.1. At least one and up to 2 SCARLET® AC-T consecutive cages between C3 and C7 levels, OR
1.2. At least one and up to 3 TRYPTIK® CA/CC cages between C3 and C7 levels, OR
1.3. At least one and up to 3 TRYPTIK® MC cages between C3 and C7 levels
2. Patient willing and able to comply with follow-up schedule and fill out questionnaires

Preoperative inclusion criteria (for Enrollment):
Patients with the surgery completed with at least one of the devices mentioned above

Patients with written voluntary informed consent signed

Participant type(s)
Patient

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 in whom cervical/radicular pain could be attributable to a diagnosis other than a degenerative disease, spondylosis, or Tryptik® CA/CC trauma, as well
3. Patients with a contraindication listed in the IFU

Date of first enrolment
19/11/2024

Date of final enrolment
23/12/2025

Locations

Countries of recruitment
France

Study participating centre
Hôpital Privé de la Miotte
15, Av. de la Miotte
Belfort
France
90000

Study participating centre
Clinique Charcot
Institut de la colonne vertébrale
49 Rue Commandant Charcot
Sainte-Foy-lès-Lyon
France
69110

Study participating centre
Clinique du Millénaire
Centre de Neurochirurgie du Millénaire
220 Bd Pénélope
Montpellier
France
34000

Study participating centre
Centre Chirurgical Orthosud
Rond-Point de l’Europe
Saint-Jean-de-Vedas

France
34430

Study participating centre
Clinique du Parc
155 Ter Boulevard Stalingrad
Lyon
France
69006

Study participating centre
Hôpital Clairval
317 Boulevard du Redon
Marseille
France
13009

Study participating centre
Medipôle Hôpital Privé
158 rue Léon Blum
Villeurbanne
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69100

Study participating centre
Hôpital Nord CHU
42 Av. Albert Raimond
Saint-Priest-en-Jarez
France
42270

Sponsor information

Organisation
Spineart (Switzerland)

ROR
https://ror.org/05sz2c652

Funder(s)

Funder type
Industry

Funder Name
Spineart SA

Results and Publications

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