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Clinical study on 15 years follow up after neck surgery with Baguera®C device.

Submission date	Recruitment status	[ ] Prospectively registered
10/03/2026	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/03/2026	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/03/2026	Musculoskeletal Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Cervical Disc Arthroplasty (CDA), also called disc replacement, aims to treat neck pain and nerve problems caused by worn or damaged discs while keeping your neck moving normally, without adding extra risks or complications.

Many studies have looked at the short- and mid-term results of disc replacement surgery, but only a few have checked what happens after more than 10 years.

For Baguera®C, previous studies have already shown positive results at 2 years, 5 years and 10 years. The goal of this study is to keep monitoring, for at least 15 years, how patients are doing after receiving the Baguera®C cervical disc implant.

Who can participate?

Only patients who participated in the previous Baguera®C study and have 5-year or 10-year follow-up data can participate in this 15-year follow-up visit.

What does the study involve?

The study includes one follow-up visit, in person or remotely. Before the visit, participants will have an X-ray as prescribed and share the images. During the visit, participants will:

* Complete pain questionnaires (VAS for arm and neck)
* Complete the Neck Disability Index (NDI) questionnaire
* Report pain medication use
* Provide cervical spine history since the last follow-up

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.

Risks not provided at time of registration

Where is the study run from?

This is an international multicenter study coordinated by Spineart SA (Switzerland) with four participating sites in France, Belgium, Spain, and Greece.

When is the study starting and how long is it expected to run for?
The study is expected to start in March 2026 and last for 4 months (June 2026).

Who is funding the study?
Spineart SA (Switzerland).

Who is the main contact?
clinic@spineart.com.

Contact information

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Public, Scientific

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Internal Reference
P16_CLD008

Study information

Scientific Title
15-year follow up after surgery with Baguera®C cervical disc prosthesis for treatment of cervical degenerative disease.

Acronym
Baguera®C 15-Year Follow Up Study

Study objectives
The aim of this study is to continue evaluating, with at least 15 years FU, the clinical and radiological outcomes of CDA with Baguera®C cervical prosthesis that has been demonstrated in patients in the 2- year Follow Up (FU) study P16_CLD001 and in the 5 & 10-year FU study P16-CLD005 .

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/02/2026, Scientific Council of Agios Loukas Clinic (3 Charilaou Trikoupi Street Panorama, Thessaloniki, 55236, Greece; +30 2310 380,000; info@klinikiagiosloukas.gr), ref: -

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Cervical disk arthroplasty (CDA) for the treatment of Symptomatic cervical disc disease (SCDD) affecting one level or two adjacent levels between C3 and C7.

Interventions
This is a single-arm, multicenter, international Post-Market Clinical Follow Up (PMCF) study without additional procedures. The study will be retrospective in France. The study will be prospective in Belgium, Greece & Spain.

The Baguera®C prosthesis is designed to preserve mobility at the treated cervical level when replacing a degenerated intervertebral disc. This is a 15-year observational follow-up of patients previously enrolled in the 5 & 10-year FU prospective study of the Baguera®C cervical disc prosthesis. All original participants will be invited for one visit.
Assessments include cervical segment mobility by radiography, pain using VAS (arm and neck), Neck Disability Index (NDI), documentation of cervical pain treatments, and adverse event review.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Baguera®C

Primary outcome(s)
1. Range of Motion (ROM) at treated level measured using dynamic X-rays at 15-year FU, as a change from baseline (historical data), as a change from 10-year FU (historical data) and according to age (above or under 50 years old at time of surgery)

Key secondary outcome(s))
1. ROM at upper adjacent level measured using dynamic X-rays at at 15-year FU, as a change from baseline (historical data), as a change from 10-year FU (historical data) and according to age (above or under 50 years old at time of surgery)

2. Disc height at upper adjacent level measured using neutral lateral X-rays (or dynamic X-rays if neutral lateral X-rays not available) at 15-year FU and as a change from baseline (historical data)

3. Pain scores measured using VAS arm and neck at 15-year FU and as change from baseline (historical data)

4. Functional capacity measured using Neck Disability Index (NDI) at 15-year FU, as change from baseline (historical data) and as a change from 10-year FU (historical data)

5. Pain medication intake for cervical pain measured using type of medication and frequency of intake at 15-year FU

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Patient who have completed at least one of the 5-year or 10-year FU visit within the P16-CLD005 study
2. Completed the 15-year FU visit

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
Patients unwilling to participate to the study, i.e.:
1. For France, have provided a written opposition for their data collection within 4 weeks after dispatch of the information letter and opposition form
2. For Belgium, Greece and Spain, have refused to sign an informed consent or withdrew consent before their 15-year FU visit

Date of first enrolment
01/03/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Belgium

France

Greece

Spain

Study participating centre
Clinique du Dos Bordeaux-Terrefort
France

Study participating centre
Hospital Clinico Universitario de Valladolid
-
-
Spain
-

Study participating centre
Saint Luke's Hospital
-
-
Greece
-

Study participating centre

Clinique du Parc Leopold
-
-
Belgium
-

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