

# Fusion rate after using an Intersomatic JULIET®TI cages in lumbar spinal surgery

<b>Submission date</b> 15/12/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/11/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/12/2024	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims:

This study will investigate the performance and safety of the JULIET®TI cage and evaluate the primary stability and the intervertebral fusion status of the lower spine using a SPEC-CT scan, in patients who received fusion surgery (joining two spinal bones, known as vertebrae) on the lower back to treat lumbar Degenerative Disk Disease (DDD), spondylolisthesis, thoracic and lumbar fractures, vertebrate tumors, or pseudarthrosis. The JULIET®TI cage is a type of prosthesis used to maintain height and decompression of the spine following this procedure. SPECT-CT has been demonstrated to provide improved diagnostic accuracy compared to CT-Scan. It will be used in this study to detect early signs of interbody fusion and adjacent levels of bone healing, following treatment with the JULIET®TI cage.

Who can participate?

Any adult patient needing treatment with a fusion system. The device is used for its intended use and patients represent the intended population.

What does the study involve?

The study involves the collection of data of patients who have received treatment with the JULIET®TI cage. Data will be collected before surgery, during the surgery for device and instrument assessment (from the surgeon), immediately after surgery, and after 3, 6, and 12 months. Questionnaires will be used to collect data on quality of life and improvements in pain and functioning. at 6 and 12 months SPEC-CT scan will be used to assess interbody fusion status.

What are the possible benefits and risks participating?

There is no direct benefit to the patient in participating in the study. Nevertheless, the post-operation SPEC-CT exams used as part of the study, compared to standard X-rays or CT scans, could have a more accurate evaluation of bone healing and diagnosis of postoperative complications that may cause pain, allowing physicians to choose targeted therapies and avoid potential unnecessary re-interventions,

There are no additional risks to the patient participating in the study versus normal clinical practice for patients being treated by JULIET Ti. The SPEC-CT vs X-rays/CT Scan and additional radiological exams requested by the protocol will consist of a total of 7,2mSv which is considered as low by the UNSCEAR.

Where is the study run from?  
Spineart (Switzerland)

When is the study starting and how long is it expected to run for?  
From October 2018 to June 2025. The study started recruitment in 2020, then was put on hold due to public health guidance at the time.

Who is funding the study?  
Spineart (Switzerland) the manufacturer of the Juliet Ti cages

Who is the main contact?  
clinic@spineart.com

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
P74\_CLD001

## Study information

**Scientific Title**  
Evaluation by SPECT-CT of early signs of interbody fusion following lumbar arthrodesis using a Titanium porous cage

**Acronym**  
JULIET-TI Observational

## **Study objectives**

Assessment of the performance, clinical benefit and safety of the device up to one year after the surgical implant, in line with MEDDEV and the New Medical Device Regulations (MDR) and used in accordance with its approved labelling.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 06/01/2020, Commission Cantonale d'Ethique de la Recherche (CCER) (rue Adrien-Lachenal 8, 1207 Genève, Suisse; 41 (0) 22 546 51 01; ccer@etat.ge.ch), ref: 2018-02376

## **Study design**

Prospective two-center single-arm post-market observational cohort study

## **Primary study design**

Observational

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

arthrodesis of the lumbar spine at one level or at two contiguous levels between L2 and S1 to treat:

1. Degenerative pathologies (recurrent hernia, degenerative spondylolisthesis, symptomatic disc disease)
2. Spondylolisthesis by isthmic lysis
3. Spine deformity (scoliosis, instability)
4. Stenosis

## **Interventions**

The study design follows a prospective methodology. It is an observational PMCF study planned to be conducted in a standard of care setting in 2 sites in Geneva, to observe patients who underwent lumbar arthrodesis (fusion surgery) using the JULIET®-TI cage for 12 months after surgery. Participants will be selected during regular consultations for lumbar pathologies and recruited by the Investigators in accordance with their normal clinical practices and the device IFU.

SPECT-CT will be carried out at 6 and 12 months post-operatively to evaluate the intervertebral fusion status. At one site, a CT scan will be carried out normally done at 6 months, and at the other site, a CT scan is normally done at 12 months.

Safety, performance, and clinical benefit will be assessed up to 12 months post-operatively. The improvement of the patient's disability, pain, and quality of life, as well as early bone metabolic signs, the instrumentation supporting the surgery, and safety will also be evaluated.

## **Intervention Type**

Device

## **Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

JULIET®-TI (titanium) cage

**Primary outcome(s)**

Interbody fusion status will be qualitatively assessed for all evaluable subjects, using SPECT-CT taken at 6 and 12 months post-surgery

**Key secondary outcome(s)**

1. Safety will be measured using adverse events (AEs), severe adverse events (SAEs), and complications recorded throughout the 12 month study period
2. Performance and clinical benefit:
  - 2.1. Disability measured using the ODI functional assessment score at baseline (pre-operative), 3, 6, and 12 months
  - 2.2. Pain measured using the VAS pain assessment score at baseline (pre-operative), 3, 6, and 12 months
  - 2.3. Quality of life (QoL) measured using the Short form-12 (SF-12) self-assessment questionnaire score at baseline (pre-operative), 3, 6, and 12 months
  - 2.4. Early bone metabolic signs of interbody fusion measured in the adjacent levels to implant by bone scan with SPECT-CT at 6 months
  - 2.5. Primary stability measured using dynamic X-ray by ROM angles between flexion/extension at baseline and
3. Instrumentation support for the following tasks: to prepare the site of implantation, to select the adequate implant, to perform the implantation, to finalize the surgery; will be evaluated in terms of safety and performance using device and instrument assessment by the surgeon during and immediately after the surgery

**Completion date**

01/06/2025

**Eligibility****Key inclusion criteria**

1. Skeletally mature patients, aged  $\leq 80$  years
2. Treated by interbody fusion with JULIET-TI at 1 or 2 contiguous levels from L2 to S1
3. Symptomatic degenerative disc disease (SDDD), Recurrent herniated disc, Isthmic spondylolisthesis, or Degenerative spondylolisthesis Grade I
4. Non-smokers or recent quitters (for  $\geq 3$  months)
5. Treated non-surgically (for  $\geq 6$  months)
6. No previous surgery at the level to be treated, or previous surgery at the level to be treated without implantation of any material (i.e. operated for herniated disc or decompression)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Upper age limit**

80 years

**Sex**

All

**Key exclusion criteria**

1. Previous surgery at the level to be treated with implantation of material (i.e. arthrodesis or arthroplasty)
2. Infection at the index level
3. Burst fracture and/or comminuted fracture of the vertebral body and/or vertebral plate
4. Osteoporosis, poor bone quality, or tumour
3. Current smokers
4. Spondylolisthesis Grade II or higher
6. Known metal sensitivity
7. Mental illness, hyperactivity
8. Neuromuscular and/or vascular disorder or illness
9. Pregnancy (current or planned next in the next 6 months)

**Date of first enrolment**

22/06/2020

**Date of final enrolment**

31/01/2024

**Locations****Countries of recruitment**

Germany

Switzerland

**Study participating centre**

**Hôpital Universitaire de Genève**

Rue Gabrielle-Perret-Gentil 4

Geneva

Switzerland

1205

**Study participating centre**

**Clinique Générale de Beaulieu Genève**

Chemin Beau-Soleil 12

Geneva

Switzerland

1206

# 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 datasets generated and/or analysed during the current study will be published as a supplement to the results publication

## IPD sharing plan summary

Published as a supplement to the results publication