Clinical Investigation Title	Evaluation by SPECT CT of early signs of interbody fusion following lumbar arthrodesis using a porous Titanium cage.
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Study design	This is a prospective, single-arm, Post-Market Clinical Follow-up (PMCF) study in two centers in Switzerland, on 55 patients who received a Juliet® Ti cage intended to provide mechanical support to the lumbar spine and maintain adequate disc space until fusion occurs. Enrollment period was between June 2020 and January 2024. The study duration went from June 2020 (first inclusion) and March 2025 (Last Patient Last Visit).
Device and study purpose	JULIET® Ti intervertebral body fusion implants are class III medical devices and have been used since 2016. They are made from medical-grade titanium using a modern 3D-manufacturing process that creates an open sponge-like surface. This design helps the implant to interact naturally with the bone. They are available in a wide variety of sizes and shapes, allowing the surgeon to choose the most appropriate implant for each patient. The JULIET® Ti devices are designed to be placed between two lumbar vertebras during surgery to help stabilize the spine and support bone fusion. The implant can be inserted using standard surgical approaches, either from the back or the side of the spine, depending on the patient's anatomy and the surgeon's preference. JULIET® Ti is intended and designed to: ▪ Support the spine mechanically after surgery ▪ Maintain the normal space between the vertebrae ▪ Hold the spine in the correct position while the bones gradually fuse together The main goal of this study is to find out whether the bones in the lower back successfully fuse together one year after surgery. Bone healing will be assessed using a specialized imaging exam called SPECT-CT, which allows doctors to see early signs of bone activity as well as a CT scan, to assess more complete fusion. In addition to bone fusion, the study also looks at the following points: ▪ Early signs of bone healing during the months following surgery ▪ Whether patients experience less pain ▪ Whether patients are able to return to daily activities more easily ▪ Improvements in overall quality of life ▪ How well the implants and supporting surgical hardware perform over time ▪ The safety of the procedure and the device, including any complications Together, these evaluations help determine whether the surgery and the implant provide meaningful benefits to patients while remaining safe over the first year after treatment.
Results and conclusion	A total of 60 subjects were screened, and 55 subjects were enrolled in the study and followed over time for about one year on average. Some patients did not complete the full study period: 8 people (about 15%) stopped early, mostly by personal choice, for other unrelated reasons, or because they could not be reached later. Most patients attended their scheduled checkups, which helped ensure reliable results: ▪ 96% attended the 3-month visit ▪ 91% attended the 6-month visit ▪ 86% attended the 12-month visit

Surgery details

The implant was placed using established surgical approaches to the spine:

- 67% through a transforaminal (side) approach
- 31% through a posterior (back) approach
- 2% using both approaches

All patients also received posterior screws to stabilize the spine. Most patients (84%) had surgery at one spinal level, while the rest (16%) had surgery at two levels. The most treated level was L4–L5, followed by L5–S1.

Performance and Clinical Benefit

Bone fusion (bone healing)

One of the main goals of spinal fusion surgery is for the bones to grow together and form a solid structure.

- By 6 months, early signs of fusion measured were seen in the majority of patients.
- By 12 months, all patients showed clear signs of solid fusion (72%) or ongoing fusion (28%). No patients showed a complete failure of fusion on the CT scans.
- Fusion success was similar for patients with one-level and two-level surgery after one year.
- Advanced imaging (SPECT-CT) confirmed that signs of bone healing increased over time and remained consistent, showing that fusion assessments were reliable.

Stability

Radiologic assessment showed that:

- The disc height was restored, meaning the space between the vertebrae improved.
- The natural curvature of the spine (lordosis) improved. These findings indicate that the spine remained stable after surgery.

Pain reduction (Back VAS score – a scale used to measure pain intensity)

Average back pain scores decreased significantly overtime:

- Pain levels decreased from moderate to severe before surgery to low pain levels by 3 months
- These improvements were maintained throughout the 12 months

Disability and daily activities (ODI questionnaire, assessing functional limitations related to back pain)

- Patients reported much lower levels of disability after surgery.
- Before surgery, the majority of the patients (almost 90%) reported moderate to severe disability.
- After one year, nearly half of patients reported only mild or minimal limitations in daily life.

Overall health and well-being (SF-12 score, a quality of life questionnaire)

The patient quality of life scores showed consistent and meaningful improvement throughout the year after the surgery.

- Physical health scores improved significantly as early as 3 months and continued to improve.
- Mental well-being also improved, especially by 6 and 12 months.
- At 12 months post-surgery, both physical and mental scores were nearing the average values of the healthy population.

Safety Results

Overall, the procedure showed a good safety profile. Some events are listed in multiple categories, and some patients experienced more than one event.

- Most patients did not experience serious complications.
- About 15% of patients had some type of adverse event.
- Serious events occurred in 18% of patients, but many were not related to the implant itself.

There were 3 device-related complications with clinical symptoms, meaning events possibly linked to the implant: 2 subsidence cases, where the implant settles slightly into the bone, and 1 infection.

Surgery-related events occurred in 14 patients including one pseudoarthrosis (lack of complete fusion between the vertebrae). This patient did not show up at the follow-up visit with the CT scan, therefore he is not included in the performance section for the fusion results. The most common events were dural tears and persistent pain, occurring in 4 patients each.

Among the above complications, a revision surgery on the device was needed for 4 patients: pseudoarthrosis associated with a stenosis, a subsidence with a cage removal, a deep infection, and a vertebral fracture. And 4 patients had a re-intervention which was related to surgical healing issues such as small fluid collections or infections, but not to device failure.

No deaths occurred during the study.

14 device deficiencies without clinical symptoms occurred in 12 patients. Those were radiological findings; patients did not feel pain or discomfort because of these findings. These included subsidence (implant settling slightly into the bone), small changes in implant position or screws, or issues related to surgical instruments.

Conclusion

After one year of follow-up, the study confirms that the JULIET® Ti implant is a safe and effective option for lumbar spinal fusion. Most of the evaluated patients experienced:

- Successful bone healing and fusion
- Improved spinal stability
- Less back pain
- Reduced disability
- Better overall quality of life
- Complications related directly to the implant were uncommon, and most observed risks were manageable within standard clinical care.

Overall, the results support the beneficial clinical performance and acceptable safety profile of the JULIET® Ti implant in real-world spinal surgery.