**JULIET® OL Study #52001**

The JULIET® OL, lumbar intersomatic poly-ether-ether-ketone cage used for symptomatic degenerative disc diseases treatment by arthrodesis. Safety and effectiveness evaluation after two years follow-up

**Investigator initiated study**
**FDA approved for this indication**
**Region: France**
**Status: Completed**

**Post CE-Marking Follow-up Study submitted to HAS (FR)**

**Primary Objectives:**
- Safety of JULIET® OL, lumbar inter-somatic cage, evaluation based on all events observed (controls, investigations, hospitalizations, interventions) during 2 year follow-up after arthrodesis.
- Overall performance of JULIET® OL, evaluated at the end of 2 years follow-up period, as a composite primary endpoint, based on data at last visit:
  - Incidence and seriousness of implant related complications
  - Absence of lumbar and radicular pain
  - Absence of neurologic disorders (sensitive and/or motor)
  - Fusion status
  - Patient satisfaction
  - Global prognostic

**Secondary objectives:**
Early qualitative effectiveness evaluation, at 2 months after surgery for lumbar arthrodesis using JULIET® OL:
- Overall success evaluated by *Stauffer* criteria:
  - Pain relief
  - Time after surgery for getting back to work
  - Diminution of physical activities
  - Pain medication
- Functional improvement evaluated by *Lassale* criteria:
  - Claudication
  - Radicular pain (at *rest* and at *effort*)
  - Lumbar pain
  - Neurologic disorders
  - Pain medication
  - Kinesitherapy
  - Time after surgery for getting back to normal life
- Radiologic criteria:
  - Implant positioning
  - Radicular compression

**Indication - condition:** Symptomatic lumbar disc degenerative disease

**Study type:** Observational, cohort, retrospective analysis

**Patients enrolled:** 27

**Primary outcomes:**
- Incidence of SAE and AE implant related
- Absence of lumbar and radicular pain
- Absence of neurologic disorders (sensitive and/or motor)
- Fusion status
- Patient satisfaction
- Global prognostic

**Secondary outcomes:**
- Changes in back and leg pain (compared to preoperative status)
- Changes in physical activities capacity (compared to preoperative status)
- Pain medication (drug’s category and frequency)
- Claudication
- Radicular pain (at rest and at effort)
- Neurologic disorders (motor and/or sensitive)
- Kinesitherapy
- Time after surgery for getting back to work
- Time after surgery for getting back to normal life
- Implant positioning
- Radicular compression
- Adverse events narratives