

Catamaran SI Joint Fusion System MAINSAIL™ Study:

**Six-month clinical outcomes and twelve-month radiographic findings:
A prospective, single-arm, multi-center, post-market investigation.**

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Study Design

The Mainsail Study is a prospective, single arm, multi-center, post-market study to **assess the safety and efficacy** of the inferior-posterior approach with the use of the Catamaran system, up to 24 months. This interim analysis presents clinical outcomes of the first **33 consecutive patients** at the **primary endpoint of 6 months**, with initial **radiographic CT fusion assessment, at 12 months**, as performed by an independent radiologist.

Key Outcomes

SUCCESS RATE:

At 6 months, **80%** of patients met the criteria for success, defined as a ≥ 20 mm reduction in SIJ pain, no serious device-related adverse events, no neurological worsening, and no surgical re-intervention.

PAIN REDUCTION:

Visual Analog Scores (VAS) SIJ pain intensity scores (0-100) significantly decreased from baseline to 6 months, 80.9mm to 31.1mm resulting in a relative improvement of **61.6%** ($p < 0.001$).

FUNCTIONAL IMPROVEMENT:

Oswestry Disability Index (ODI) scores significantly improved from baseline to 6 months, 51.9% to 29.6% resulting in a relative improvement of **43%** ($p < 0.01$).

Key Outcomes (Cont.)

SAFETY:

No serious adverse events, no reoperations, and no reinterventions reported. No vascular or nerve injuries associated with the use of the inferior-posterior surgical approach used to deliver the Catamaran implant.

PATIENT SATISFACTION:

93.3% of patients reported high satisfaction with their treatment at 6 months.

FUSION RADIOGRAPHIC OUTCOMES:

12-month follow-up with CT radiographic imaging, 4 of the 6 patients demonstrated fusion with bridging bone as performed by an independent radiologist.

EFFICIENT SURGICAL TECHNIQUE & PROCEDURAL WORKFLOW:

- 55% of procedures were completed in under 45 minutes, with shortest procedural time recorded as 24 minutes.
- 50% of procedures utilized < 1 minute of fluoroscopy time.
- All procedures were performed in an outpatient setting.

INNOVATIVE DESIGN

Catamaran SI Joint Fixation Device is a single implant fabricated from medical grade titanium alloy and comprised of two hollow pontoons, connected via osteotome bridge. Through a minimally invasive inferior-posterior approach the Catamaran implant is delivered within the dense cortical bone of the sacrum and ilium, to transfix, stabilize and promote arthrodesis of the SI joint.



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