

Evaluation of the iFuse Bedrock Technique in Association with Posterior Lumbosacral Fusion with Iliac Fixation.

NCT05276024

Status	RECRUITING
Sponsor	Polyclinique Bordeaux Nord Aquitaine
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (4)

- Subject scheduled for open posterior lumbosacral arthrodesis (including at least the following three vertebrae: L4, L5 and S1) associated with a sacroiliac fusion procedure and iliac fixation (thoracolumbar fusion procedures extended to sacrum are eligible in the study);
- Insertion of at least 1 iFuse-3D implant according to the iFuse Bedrock technique (uni- and bilateral insertion are eligible);
- Subject who preoperatively responded positively to pain provocation tests for SIJ dysfunction with or without a positive SIJ infiltration test;
- Patient with a degenerative sacroiliac joint disease requested a fusion procedure;

Exclusion (8)

- Major osteoporosis (DEXA scan ≤ -3);
- Any previous history of sacroiliac joint fusion or any surgical procedure involving a S2-iliac fusion;
- Subjects requested a SIJ fusion without the iFuse-3D device or iFuse-3D not inserted according to the manufacturer instruction (Bedrock technique);
- Subjects with a medical or surgical contraindication preventing the intervention from being performed or potentially interfering in the interpretation of the data collected (neurologic condition, local or systemic infection, any known allergy to surgical implants, psychiatric diseases, ...);
- Currently pregnant or planning pregnancy;
- ... and 3 more (see full listing online)

Locations (2 total)

Polyclinique Bordeaux Nord Aquitaine, Bordeaux, France
Hôpitaux Universitaires de Marseille, Marseille, France