1 Structured Abstract:

2 Background Context:

- 3 Sacroiliac joint (SIJ) fusion was traditionally performed exclusively by spine surgeons using an
- 4 open direct lateral approach. With advancements in technology, SIJ fusion has evolved into a
- 5 minimally invasive percutaneous technique, potentially reducing associated risks. Interventional
- 6 Pain Management (IPM) physicians have adopted these technique due to their expertise in
- 7 interventional procedures. This rise in SIJ fusions by untrained IPM physicians has raised patient
- 8 safety concerns among spine surgeons. With the expanding role of IPM physicians, their
- 9 involvement in SIJ fusion, particularly using transfixation implants through a posterior-oblique
- approach, has not been thoroughly explored.

11 Purpose:

- 12 To evaluate and compare the safety and efficacy of percutaneous posterior-oblique SIJ fusions
- performed by trained IPM physicians using the Sacrix[®] titanium triangular implant (STTI)
- 14 (Sacrix LLC, Burlington, MA, USA), under direct spine surgeon supervision versus non-spine
- 15 surgeon supervision.

16 Study Design/Setting:

- 17 A prospective, randomized, controlled multicenter cohort study conducted across multiple
- ambulatory surgery centers between 2020 and 2022.

Patient Sample:

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20 276 adult patients (mean age 56.7 years; 72.1% female) scheduled for SIJ fusion.

Outcome Measures:

- 2 The primary outcome measures were surgical complications, deviations, and revisions. These
- 3 were assessed through medical records and radiographs for at least 6 months post operative.

4 Methods:

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- 5 Participants were randomly assigned to the spine surgeon supervised (control) group 1 or the
- 6 non-surgeon supervised group 2. The latter was further divided into subgroups supervised by
- 7 either clinical specialists or sales representatives/independent distributors. All IPM physicians
- 8 received comprehensive training on the Sacrix[®] technique by a board-certified orthopedic spine
- 9 surgeon. Surgical complications, deviations, and revisions were recorded, with follow-up data
- 10 collected for at least twelve months.

Results:

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- 12 Control group 1 (n = 66) reported no complications, deviations, or revisions. In group 2 (n =
- 13 210), 9 complications (3.3%), 4 deviations (1.4%), and 5 revisions (1.8%) were identified,
- occurring between the second and fifth postoperative days. Statistical analysis revealed no
- significant differences between groups 1 and 2 in complications, deviations, or revisions
- 16 (P=0.189, P=0.575) and P=0.343, respectively). The relative risk between non-surgeon
- supervised subgroups was 1 (95% CI 0.31–3.14), indicating no significant difference in risk.

Conclusions:

- 19 Trained IPM physicians safely performed percutaneous SIJ fusions using the Sacrix® technique,
- 20 achieving low complication and revision rates similar across both spine surgeon-supervised and
- 21 non-surgeon-supervised groups. Notably, direct spine surgeon supervision further minimized

- 1 intraoperative complications. This study highlights the effectiveness of certifiable training and
- 2 mentorship by a spine surgeon in enabling IPM physicians to proficiently perform SIJ fusions.
- 3 **Keywords**: Sacrix[®], SI-Bone, iFuse, Sacroiliac Joint Fusion, SIJ Fusion, Titanium Triangular
- 4 Implant, Posterior-Oblique, Interventional Pain Medicine.

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