

RELEASABLE
SUMMARY OF SAFETY AND EFFECTIVENESS
TRANSFACETPEDICULAR SCREW FIXATION SYSTEM
K953076

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- I. **Company:** Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
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- II. **Proprietary Trade Name:** TRANSFACETPEDICULAR Screw Fixation System

- III. This system consists of a broad-headed, partially threaded screw designed to compress bone grafts. Both cortical and cancellous screw threads are available. The stainless steel DYNA-LOK® Plates are used as spinous process plates to connect two or more screws together on one side of the spine at the base of the spinous processes when the system is used for the second fixation method described below. All components are fabricated from medical grade stainless steel (ASTM F-138 or its ISO equivalent).

- IV. **Indications:** The TRANSFACETPEDICULAR Screw Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods. The first fixation method uses the TRANSFACETPEDICULAR Screws as just facet fixation screws, where the screws are inserted bilaterally through the superior side of the facet, across the facet joint at (usually) a single level, and into the pedicle. In the second fixation method, the TRANSFACETPEDICULAR Screws are inserted bilaterally through the superior side of the facet, across the facet joint, and into the pedicle at multiple levels at the same time that a DYNA-LOK® Plate is attached to the base of the spinous processes at the corresponding levels with TRANSFACETPEDICULAR Screws. The second fixation method should be used when the spine has increased instability or multiple levels need to be fused. Bone graft must be used for both fixation methods.

This system is indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels:

1. Trauma, including spinal fractures and/or dislocations.
2. Spondylolisthesis.
3. Spondylolysis.

4. Pseudarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity.
 5. Degenerative diseases which include:
 - (a) degenerative disc disease (ddd) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or
 - (b) degenerative disease of the facets with instability.
- V. Literature and other documentation concerning this device system were supplied in support of establishing a claim of substantial equivalence and the preamendment status of a predicate device system.