

**Attachment IX: Summary of Safety and Effectiveness Information**

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Synthes SSEF is compared to the EBI's Orthofix Penning Dynamic Wrist Fixator.

The Synthes SSEF stabilizes fractures of the distal radius. The components that make up a SSEF frame include the Schanz screws, adjustable clamps, rods, and end caps. It is anticipated that the most common use of the device would be as follows:

1. A small incision is made over the second metacarpal and radius.
2. Using the Parallel Drill Guide for soft tissue protection and positioning, a pair of Self-Drilling Schanz Screws are inserted into the second metacarpal and radius.
3. An adjustable clamp is slid over each pair of Schanz Screws and tightened to lock on the pins.
4. An appropriately sized rod is slid through each clamp.
5. End caps are applied to each end of the rod to captivate the clamps.
6. The fracture is reduced.
7. The remaining screws on both adjustable clamps are tightened to hold the reduction.

The adjustable clamps of the SSEF are manufactured from a titanium alloy and stainless steel. The rods of the SSEF are manufactured from carbon fiber reinforced epoxy and the end caps of the SSEF are manufactured from polyvinyl chloride.

The EBI's Orthofix Penning Dynamic Wrist Fixator also stabilizes fractures of the distal radius. It is manufactured from stainless steel and anodized aluminum.

Based on the results of the mechanical testing, Synthes SSEF is at least equivalent to the EBI's Orthofix Pennig Dynamic Wrist Fixator in performance.