

Attachment VII: Summary of Safety and Effectiveness Information [510(k) Summary]

SYNTHES (USA)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700
Contact: Angela Silvestri
July 1996

Device: Synthes Dorsal Distal Radius Plate is compared to the Zimmer Small T-Plate, Oblique.

Synthes Dorsal Distal Radius Plate is intended for fixation of fractures, osteotomies and carpal fusions involving the distal radius, applied to the dorsal aspect. It is manufactured from a Titanium alloy.

Synthes Dorsal Distal Radius Plate is PI shaped, with two proximal arms (shaft) and one distal arm (head). The plate is precontoured, and is available in right and left versions. The plate can be cut to size, and there are four compression holes and one round hole in each proximal arm (shaft) that accept 2.7 mm cortex screws, and seven internally threaded holes in the distal arm (head) that accept 1.8 mm threaded head buttress pins or 2.4 mm cortex screws.

The Zimmer Oblique T-Plate is intended for condylar fixation.

Synthes Dorsal Distal Radius Plate is at least equivalent to the Zimmer Small T-Plate, Oblique based on the mechanical test results of both devices.