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

SYNTHES (USA)  
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PAR - 8

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Device: Synthes Volar Distal Radius Plate is compared to Synthes Small T-Plate.

Synthes Volar Distal Radius Plate is intended for fixation of fractures and osteotomies of the distal radius, applied to the volar aspect. It is manufactured from commercially pure titanium. The plate is T-shaped, with the head 10° from perpendicular to the shaft, is pre-contoured, and is available in right and left versions. The head can be cut to size; it has up to six threaded holes, and accepts either 2.4 mm Cortex Screws or 1.8 mm Buttress Pins. The shaft can also be cut to size, and has up to five compression holes, two being elongated shaft holes to facilitate positioning, and accepts 2.7 mm Cortex Screws.

Synthes Volar Distal Radius Plate will be provided both sterile and non-sterile. The sterile device will be sterilized by gamma radiation. Of course, non-sterile devices must be sterilized prior to use; moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline "Good Hospital Practice: Steam Sterilization and Sterility Assurance." The recommended steam sterilization parameters for the non-sterile device are as follows:

<u>Method</u>	<u>Cycle</u>	<u>Time</u>	<u>Temperature</u>
Steam	Pre-vacuum	6 minutes	132° - 135°C
Steam	Gravity Displacement	15 minutes	132° - 135°C

The Synthes Small T-Plate is also intended for fixation of fractures and osteotomies, including, but not limited to, the distal radius. It is manufactured from 316L stainless steel. This plate is also T-shaped, is pre-contoured, and is reversible for right and left application. The plate can be cut to size, and has round head and shaft holes (with an elongated shaft hole) that accept 3.5 mm Cortex Screws and 4.0 mm Cancellous Screws.

Based on the results of mechanical testing, Synthes Volar Distal Radius Plate is at least equivalent to the Synthes Small T-Plate.