SYNTHES®

K963798

Attachment VIII: Summary of Safety and Effectiveness Information

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Synthes Ti Alloy VDRP is compared to Synthes VDRP and Synthes STP.

Synthes Ti Alloy VDRP is intended for fixation of fractures and osteotomies of the distal radius, applied to the volar aspect. The plate is T-shaped (with the head 10° from perpendicular to the shaft), pre-contoured, and available in right and left versions. The head can be cut to size, and has up to six threaded holes that accept either 2.4 mm cortex screws or 1.8 mm buttress pins. The shaft can also be cut to size, has up to five compression holes (two being elongated shaft holes to facilitate positioning), and accepts 2.7 mm cortex screws. As is stated in its name, the plate is manufactured from a Ti Alloy.

Synthes Ti Alloy 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 VDRP is identical to the device described above but it is manufactured from CP Titanium.

The Synthes STP 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 Ti Alloy VDRP and Synthes VDRP is at least equivalent to the Synthes STP.