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**Summary of Safety and Effectiveness Information**

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**Device:** Synthes Anatomical Locking Plate System (ALPS) compared to Synthes PC-Fix, Condylar Plate 95°, Condylar Buttress Plate, 4.5 mm Cortex Screws, and 6.5 mm Cancellous Screws

Synthes ALPS is a plate and screw system intended to treat fractures of various long bones, including the radius, ulna, humerus, tibia, fibula and femur. The ALPS utilizes a locking feature that secures the screw to the plate, enabling stable fixation to be achieved via unicortical or bicortical fixation. The plates are available with and without an anatomically contoured head, in a variety of sizes. The head of the screw has a round cross section with a conical underside to fit into the plate. The underside has a tapered thread to match the design of the holes in the plate. The screws are available in thread diameters from 3 mm to 5 mm, in a variety of lengths.

It is anticipated that the ALPS will be used as follows:

- a) The plate is percutaneously inserted through a stab incision at either the distal or proximal end of the bone.
- b) The fracture is reduced and temporary fixation may be applied.
- c) The Insertion Guide is first attached to a screw hole at the head of the plate (the last screw hole on either end of the shaft plate) using the Connecting Screw.
- d) The distal end of the plate is then inserted into the incision first. This end is tapered and rounded to gently lift and separate tissue.
- e) The plate is manipulated using the insertion handle.
- f) Once the plate is in position the ALPS screw can be inserted.
- g) The Insertion Sleeve and Trocar are placed through one of the aiming holes. The trocar perforates the skin and facilitates the sleeve positioning to the corresponding screw hole in the plate. The trocar is removed from the sleeve.
- h) The screwdriver, with a screw attached, is then inserted through the sleeve.
- i) The screw is inserted into the bone securing the plate.
- j) After tightening the screw to the plate, the function of the implant and fixation will not be jeopardized if the plate is not flush against the bone.
- k) After the screws are in place the Insertion Guide is removed.
- l) An additional screw can be placed in the screw hole that secured the Insertion Guide if necessary.

Synthes Anatomical Locking Plate System 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.

Based on the results of confidential testing, it is our opinion that the ALPS is substantially equivalent to the devices with which it is being compared.