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Attachment D: Summary of Safety and Effectiveness

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Synthes High Tibial Osteotomy (HTO) System is compared to Howmedica's Alta Metaphyseal L-Plate and 3.7 mm Cortex Screws and 4.2 mm Cancellous Screws

Synthes HTO System is an instrument and implant system intended for high tibial osteotomies to correct leg malalignments causing unicompartmental osteoarthritis. The HTO System 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 an anatomically contoured head. The head of the 5.0 mm locking screw has a round cross section with a threaded conical underside to fit into the plate. The underside has a tapered thread to match the design of the holes in the plate. The locking screw is available in lengths ranging between 26 and 65 mm. Standard 4.5 mm cortex screws (lengths 80 - 100 mm) and 4.5 mm shaft screws (lengths 80 - 100 mm) are also available for use with the plates.

The following briefly describes the insertion of this device:

- a) The Linear Saw Guide is positioned over two K-wires which have been anatomically located. The depth of the bone is measured through the guide and the desired cutting depth is set. The oscillating saw blade is inserted through the guide and cuts are made at the desired angles. The Linear Saw Guide and K-wires are then removed.
- b) The insertion guide is attached to the HTO System plate via a threaded hole in the plate. The attachment of an insertion guide will facilitate the coaxial alignment of the screw and plate during screw insertion.
- c) The plate is inserted after the osteotomy is performed. The most distal end of the plate will be inserted first. This end features a tapered rounded section, which will serve to gently lift up and separate tissue allowing the plate, via the insertion guide, to be manipulated to the bone surface. This insertion process will reduce soft tissue stripping.
- d) An insertion sleeve will then be inserted into the insertion guide. The sleeve facilitates the alignment of the screw driver, the screw and the plate.
- e) Once in place, bridging the osteotomy, the most proximal anterior screw will be inserted first.
- f) The closing forceps are then attached to the distal fragment (via HTO screw) and to the insertion guide. The insertion guide is still attached to the plate which is secured to the proximal fragment. The instrument is slowly manipulated to bring the distal fragment into proper alignment.
- g) Upon achieving proper alignment the remaining screws are inserted.
- h) A standard 4.5 mm cortex screw is inserted into the most proximal posterior hole to achieve interfragmental compression across the osteotomy site.

Based on the results of confidential testing, it is our opinion that the HTO System is substantially equivalent to Howmedica's Alta Metaphyseal L-Plate.