



K953777

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

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Device: Synthes Wire Mount is compared to Synthes Cerclage Wire.

Synthes Wire Mount is intended for use with cerclage wire to augment fracture stabilization with plates when use of screws is contraindicated, as in the presence of intramedullary implants. The design is a "T" post with a hole perpendicular to the post axis, and a small triangular ridge on the bottom. Placing the post through the dynamic compression screw hole, inserting from the bone side of the plate, creates a stable structure for cerclage wire fixation. The cerclage wire is passed around the bone, through the Wire Mount hole above the outer surface of the plate, and then twisted with the opposite wire end.

The device is designed for use in dynamic compression screw holes that accept a 4.5 mm bone screw. Among the plates the Wire Mount (and cerclage wire) can be used with include, but are not limited, to Dynamic Hip Screw (DHS), Dynamic Condylar Screw (DCS), Condylar Buttress, Cobra Head, Hook, 4.5 mm Narrow, Broad Dynamic Compression (DCP), 90° Child and Adolescent Osteotomy, 110 - 130° Adult Osteotomy, 95° Condylar (including small stature plates) and 130° Angle Blade Plates (including small stature plates). The Wire Mount is manufactured from 316L stainless steel.

Synthes Cerclage Wire is a straight wire that is also intended to augment fracture stabilization with plates when use of screws is contraindicated, e.g., in the presence of intramedullary implants. Among the plates the Cerclage Wire can be used with include, but are not limited to, DHS, DCS, Condylar Buttress, Cobra Head, Hook, 4.5 mm Narrow, Broad DCP, 90° Child and Adolescent Osteotomy, 110 - 130° Adult Osteotomy, 95° Condylar (including small stature plates), and 130° Angle Blade Plates (including small stature plates). It is also manufactured from 316L stainless steel.

Synthes Wire Mount (with cerclage wire) is at least equivalent to Synthes Cerclage Wire, based on the results of the testing of both devices.

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