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Attachment V: Summary of Safety and Effectiveness Information

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Synthes DHS/DCS One-Step Lag Screws are compared to Synthes Ti DHS/DCS Lag Screws and Synthes DHS/DCS Lag Screws.

Synthes DHS/DCS One-Step Lag Screws are designed for use with the Dynamic Hip Screw (DHS) Plates and Dynamic Condylar Screw (DCS) Plates. They are intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed.

Synthes DHS/DCS One-Step Lag Screw has a 12.7 mm or a 14.0 mm thread diameter and is available in various lengths. The DHS/DCS One-Step Lag Screw is manufactured from stainless steel.

Additionally, Synthes Ti-DHS/DCS One-Step Lag Screw and DHS/DCS Lag Screws have a 12.7 mm or a 14.0 mm thread diameter and are available in various lengths. The Ti-DHS/DCS One-Step Lag Screw is manufactured from Titanium Alloy. The DHS/DCS Lag Screw is manufactured from stainless steel.

Synthes DHS/DCS One-Step Lag Screw will be provided sterile; gamma radiation will be used to sterilize the device.

Based upon the information identified above, Synthes DHS/DCS One-Step Lag Screw is equivalent to Synthes Ti-DHS/DCS One-Step Lag Screw and Synthes DHS/DCS Lag Screw.