

K960704

SUMMARY OF SAFETY AND EFFECTIVENESS

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NAME OF FIRM: DePuy Inc.
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TRADE NAME: Advantage Magnum Interference Screws

CLASSIFICATION NAME: Smooth or threaded metallic bone fixation fastener

COMMON NAME: Bone/tendon/bone interference fixation screw

SUBSTANTIALLY EQUIVALENT

DEVICE: DePuy M. Kurosaka Interference Screws

DEVICE DESCRIPTION:

The Advantage Magnum Screw is a fully threaded, cannulated, Titanium alloy, cancellous bone screw, available in diameters of 11, 13 and 15mm and in lengths of 15, 20, 25 and 30mm. The tip of the screw is tapered to a point which produces the self-tapping feature of the screw. The screw is inserted by a hex drive which is broached into the minor diameter of the screw itself which minimizes the size of the head of the screw. The headless, low profile design minimizes subcutaneous surface protrusions. The large cancellous threads are a symmetrical thread form with a smooth radius at the base of the threads.

INTENDED USE:

The Advantage Magnum Interference Screws are intended to provide early rigid fixation and stability of the bone block in bone/ patellar tendon/ bone graft surgical procedures for Anterior Cruciate Ligament (ACL) reconstruction. They are specifically intended for use in bone tunnels which have been enlarged due to tunnel/graft mismatch or revision of a prior ACL reconstruction.

SUBSTANTIAL EQUIVALENCE:

The Advantage Magnum Interference Screws are manufactured from the same material and have the same intended use as the DePuy M. Kurosaka Interference Screws. The only significant difference between the two designs is that the Advantage Magnum Interference Screws have larger diameters and are available in a shorter length than the M. Kurosaka Screws. Due to their increased diameter, the mechanical performance of the Advantage Magnum Screws is expected to be equal to or better than that of the M. Kurosaka Screws.

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