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Summary of Safety and Effectiveness

Smith & Nephew Orthopaedics

Ilizarov External Fixation System - Titanium Washers, Titanium Wires, and Titanium Wires with Olive Shaped Stopper

The titanium washers and titanium wires of the Ilizarov External Fixation System are single use devices designed for patients with the following indications: open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of bony or soft tissue defects. Titanium washers are intended to be used for fixation to distribute the load of the wire with stopper, for the diagnostic indications of osteoporotic bone. These components as part of the Ilizarov External Fixator System are for the diagnostic indications of fractures, pseudoarthrosis and correction of segmental or nonsegmental bony or soft tissue deformities.

The titanium wires and washers have the same function as the existing stainless steel wires and washers. They are made of titanium for patients who have a sensitivity to stainless steel. The titanium components are primarily for patients that have allergy sensitivities.

The washer and wires interconnect with the Ilizarov External Fixator System. The wires are inserted and attached to the rings of the circular fixator and rods of the Ilizarov External Fixator System. The wires are available with an olive shaped stopper to create interfragmentary compression or to add more stability to the assemblage. The washer may be used with the wires with stopper to provide surface area for the stopper to push up against.

The testing of these devices centered primarily on the following parameters: fatigue testing of the titanium wires. The results were acceptable and the titanium wire should perform as well as the stainless steel wire.