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Summary of Safety and Effectiveness**Smith & Nephew Inc. Orthopaedic Division**

K970748

Taylor Spatial Frame External Fixation System

The Taylor Spatial Frame (TSF) external fixator and its components are indicated for 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 segmental or nonsegmental bony or soft tissue defects. The TSF is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

Fixator Construct Classification:	Long Bone / Limb Lengthening
Frame Limb Access Classification:	Circular
Frame Pin Configuration Classification:	Multi-plane

The TSF is intended for fixation of fractures of long bones including intracapsular, intertrochanteric, supracondylar, or condylar. It is also used for joint fusions and limb lengthening or deformity corrections which involve cutting of the bone.

The TSF is not intended for use in the spine, and it does not claim dynamization benefits or MRI compatibility.

The TSF consists of full or partial rings coupled by six telescopic struts which terminate at each end by articulating ball joints. The components of the Taylor Spatial Frame External Fixator are intended to be used with pins, wires and washers of the Ilizarov External Fixator System. The half-pins, wires and washers of the Ilizarov system are inserted into the affected limb. The wires are tensioned and attached to the TSF ring of the TSF frame using an Ilizarov fixation bolt. Half-pin fixation is occasionally used instead of wires. An adjustable half-pin clamp allows for the orientation of the insertion of the half-pins or femoral screws. A universal joint may be used in cases where movement is necessary. Rancho cubes are available for half-pins combined with TSF rings.

The devices are for single use. Cementless or cement fixation is not applicable to this device. These devices have not been submitted to the FDA for identical or different intended uses.

A software program is included with the surgical technique. To template or guide the device, a software program is used to assist the surgeon and is equivalent to performing manual calculations to obtain the numbers necessary to adjust the 6 telescopic struts and apply the TSF external fixation device.