

Attachment VI: Summary of Safety and Effectiveness Information

K962484

Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, PA 19301

(610) 647 - 9700
Contact: Angela J. Silvestri
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Synthes Ti External Fixator Clamps are compared to Synthes Hybrid External Fixator clamps, Synthes Titanium Universal Clamp, and Synthes Ti Tube to Tube Clamp.

Synthes Ti External Fixator Clamps are used in the construction of an external fixation frame for the treatment of long bone fractures that require external fixation. The Ti External Fixator Clamps are manufactured from Titanium-6% Aluminum-7% Niobium (Ti-6Al-7Nb) or a Titanium-6% Aluminum-4% Vanadium (Ti-6Al-4V) alloy.

Based on the mechanical properties for the Ti-6Al-7Nb material, the External Fixator Clamps will perform at least equivalent to Ti-6Al-4V External Fixator Clamps.