

MAY - 8 1996

K960782

Attachment VII: Summary of Safety and Effectiveness Information [510(k) Summary]

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 Tube to Tube Clamp is compared to Ace Medical's Articulation Coupler.

Synthes Ti Tube to Tube Clamp is intended for use in the construction of an external fixation frame for the treatment of long bone fractures that require external fixation. The clamps attach the two carbon fiber rods or stainless steel tubes. The device is manufactured from a Titanium Alloy.

Ace Medical's Articulation Coupler is intended for use in the construction of an external fixation frame for the treatment of long bone fractures that require external fixation. The clamps attach the two rods. The clamps attach the two carbon fiber rods or stainless steel tubes. The device is manufactured from a Titanium Alloy.

Based on mechanical test results, the Ti Tube to Tube Clamp has been found to be substantially equivalent to the Articulation Coupler.