



K962047

Attachment VII: Summary of Safety and Effectiveness Information

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Synthes Titanium Cannulated Tibial Nail (Ti CTN) is compared to Synthes Ti-6Al-7Nb Unreamed Tibial Nail and is an extension to Synthes Titanium Tibial Nail System.

Both devices mentioned above are intended to stabilize fractures of the tibia. Indications include, but are not limited to, open and closed tibial shaft fractures, certain pre- and post-isthmic fractures, tibial malunions and tibial non-unions.

The Synthes Ti CTN is available in sizes ranging from 11 mm to 14 mm in diameter and in lengths ranging from 255 mm to 420 mm. The nail has a cannulated tube with a bend in the sagittal plane which facilitates insertion into the tibia. There are four locking holes proximally and three locking holes distally. All of the locking holes accept 4.9 mm Titanium Locking Bolts.

The devices will be provided both sterile and non-sterile. The non-sterile devices must be sterilized prior to use. The following sterilization parameters are recommended:

<u>Method</u>	<u>Cycle</u>	<u>Time</u>	<u>Temperature</u>
Steam	Pre-Vacuum	6 minutes	132°C - 135°C
Steam	Gravity Displacement	15 minutes	132°C - 135°C