



K954385

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

SYNTHES (USA)  
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Device: Synthes Mandibular Modular Fixation System, as compared to the W. Lorenz Würzburg Titanium Miniplate System.

The Synthes Mandibular Modular Fixation System is a plate and screw system, manufactured from commercially pure titanium, and is intended for use in:

- Oral, maxillofacial surgery: trauma; surgical correction of dentofacial deformities; reconstructive surgery; and craniofacial surgery
- ENT: trauma of the nasal bones
- Neurosurgery: osteosynthesis of the cranial bones.

The plates are available in a variety of shapes and sizes and attach to bone via 2.0 mm, 2.4 mm, or 2.7 mm self-tapping screws.

The W. Lorenz Würzburg Titanium Miniplate System, manufactured from titanium, and is intended for use in the following:

- Oral, maxillofacial surgery: trauma; surgical correction of dentofacial deformities; reconstructive surgery; and craniofacial surgery
- ENT: trauma of the nasal bones
- Neurosurgery: osteosynthesis of the cranial bones

The plates are also available in a variety of shapes to accommodate various fracture types, and attach to bone via 2.0 mm or 2.3 mm self-tapping screws.

Synthes will provide the device non-sterile. Of course, non-sterile devices must be sterilized prior to use; moist heat sterilization is recommended.

Based on mechanical test results, the Synthes Mandibular Modular Fixation System is substantially equivalent to the W. Lorenz Würzburg Titanium Miniplate System.