

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

Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301

Contact: Angela Silvestri  
(610) 647-9700  
June 1996

Synthes Mandible Distractor is compared to the Howmedica's Hoffmann® Mini-Lengthening Fixator (K792561). The device is similar to Howmedica's Mandibular Bone Distractor (K945674).

The Synthes Mandible Distractor is intended to be used in the mandible for conditions such as mandibular deficiency or post-traumatic effects of the mandible, where gradual bone distraction is required.

The Mandible Distractor is a subcutaneous bone distractor. It features two telescoping components activated by a jack screw, fixed to the bone via subcutaneous plates and secured with 2.0 mm or 2.4 mm bone screws. A hex driver is used to activate the required distraction.

It is anticipated that the Mandible Distractor will be used as follows:

1. An osteotomy or corticotomy (depending on surgeon preference) is made on the desired section of the mandible.
2. The distraction device is fixated to the bone using 2.0 mm or 2.4 mm screws on both sides of the osteotomy. The fixation portion of the device is subcutaneous.
3. After a latency period of approximately 7 days (the exact time required is determined by the surgeon) the device is activated and distraction begins at a rate of approximately 1 mm/day (the exact rate of distraction is determined by the surgeon).
4. After the desired amount of distraction occurs the device is left until the adequate bone structure has been achieved and the device is removed.

It is our opinion that Synthes Mandible Distractor is substantially equivalent to Howmedica's Hoffmann® Mini-Lengthening Fixator based on mechanical test results.