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SUMMARY OF SAFETY AND EFFECTIVENESS

The LactoSorb® Trauma Plating System is indicated for use in trauma and reconstructive procedures in the midface and craniofacial skeleton.

1. Comminuted fractures of the naso-ethmoidal and infraorbital areas.
2. Comminuted fractures of the frontal sinus wall.
3. Trauma of the midface or craniofacial skeleton.
4. Reconstructive procedures of the midface or craniofacial skeleton.

This system is not designed for use in the mandible and/or full load bearing procedures.

The LactoSorb® implants are made of bioresorbable and biocompatible polymer that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic (PLA/PGA) acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when the FDA first approved the use of resorbable PLA/PGA sutures. The exact same LactoSorb® material has been implanted in humans for over 10 years in Poly Surgiclip® device manufactured by United States Surgical Corporation. The LactoSorb® material has been found to be biocompatible in both soft and hard bone tissue.

The effectiveness of this resorbable system was determined by mechanical testing and an FDA approved clinical study. The LactoSorb® system was found to provide adequate fixation in the craniomaxillofacial region. This system is as effective as similar metal micro fixation systems on the market. The devices completely resorb by 12 months IN VIVO eliminating the need for long-term removal.