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SUMMARY OF SAFETY AND EFFECTIVENESS

The Biomet Bone Screw is indicated for ankle fractures, metatarsal fusions and metatarsal osteotomies (Hallux Valgus).

The screws are made of a resorbable copolymer comprised of polylactic acid (PLA) and polyglycolic acid (PGA). In histological animal studies, the bone screw was completely resorbed by 15 months IN VIVO.

The Biomet Bone Screw is made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic 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 a ligating clip. The LactoSorb® material has been found to be biocompatible in both soft tissue and bone tissue.

The effectiveness of the Biomet Bone Screw was determined by mechanical testing. The LactoSorb® screws were found to provide the same healing as a stainless steel screw in an animal model. There was no adverse tissue response to either the metal or LactoSorb® screws.

In summary the Biomet Bone Screw is safe and effective for fixation of cancellous bone. Mechanical testing demonstrated the Biomet Bone Screw to be as effective as the comparative metal and PGA resorbable cancellous screw.