K970031

Summary of Safety and Effectiveness

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Trade Name: Tibial Component

Common Name: Tibial Component

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis.

Description: The resurfacing and pegged tibial components are available in six sizes, articulate with the existing Foundation® Knee System. The baseplates are fabricated from wrought Ti-6Al-4V that conforms to ASTM F136. The under side of both baseplates is plasma sprayed with commercially pure titanium to provide a roughened surface to enhance cement fixation. The resurfacing baseplate has four smooth pegs and two screw holes to allow the use of 6.5 mm cancellous type screws. The resurfacing component has a notch cut out posteriorly to allow retention of the posterior cruciate ligament. The stemmed tibial baseplate has a stem for rotational stability and four screw holes.

Indications: The indications for use of these tibial inserts are noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis, avascular necrosis of the femoral condyle, post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus or flexion deformities, rheumatoid arthritis, treatment of fractures that are unmanageable using other techniques. This device is for cemented use only.

Comparable Features to Predicate Device(s): This device is similar in features, design and indications as the Foundation® Primary Knee System (K923277) and Biomet Maxim® Knee System.