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K963028

Summary of Safety and Effectiveness

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Trade Name: Tibial Insert

Common Name: Tibial Insert

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

Description: This component is available in seven sizes to fit into, and articulate with, the existing Foundation Baseplates and Femoral Components. This device is used in conjunction with the Foundation® Tibial Baseplates and Femurs. This insert is intended to provide more congruency between the insert and femur than is available with the primary insert. However, it will provide similar, or slightly more, congruency than the Foundation® Posterior Stabilized Knee. Anterior/posterior stability is greater than the primary insert because of the increased height of the anterior and posterior lips. Rotational stability is similar to the primary insert.

Indications: The indications for use of this tibial insert 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.

Comparable Features to Predicate Device(s): This device is similar in features, design and indications as the Foundation® Primary Knee System (K923277) and Foundation® Posterior Stabilized Tibial Inserts. (K933539)