SECTION II - DEVICE INFORMATION

A. General Device Description and Use

The modern history of knee arthroplasty began in the 1940's, and there has been remarkable improvement in prosthesis function since that time. Progress through interpositional arthroplasty, hemiarthroplasty, hinged knees, total condylar arthroplasty, and different posterior cruciate ligament treatments has inched the science of knee arthroplasty closer to a more satisfactory replacement for the natural knee. However, even in the most highly evolved designs of fixed bearing knees there is an intrinsic conflict between the need for dispersing contact forces over a greater range of the polyethylene tibial component in order to reduce wear, and the reduction in mobility that results from the more highly conforming polyethylene.

The introduction of mobile bearing knees in the late 1970's was intended to address this "kinematic conflict" with designs that combined a highly conforming surface and a mobile polyethylene tibial component. The highly conforming surface disperses contact stresses over a greater area, thus potentially reducing wear. At the same time, the mobile polyethylene bearing allows a degree of motion that has the potential to reduce implant-to-bone interface stresses. Such stresses have been shown to lead to implant loosening in highly conforming fixed-bearing knee designs.

The defining feature of a "mobile bearing knee" is the presence of a moving polyethylene bearing that articulates with both the femoral condyle and the tibial tray.

Today, there are nearly fifty mobile bearing knee designs in use, the majority outside the U.S. They utilize a number of design variations that attempt to achieve low contact stress while maintaining near natural mobility. These design variations, and the approaches to them, include:

- Type of Bearing Surface:

  <u>Platform:</u> a single polyethylene bearing that rotates in the transverse plane, with or without A/P motion (rotating only or multidirectional platform – see Figures B, C and E).

  <u>Meniscal Bearing</u>: separate medial and lateral polyethylene bearings that slide independently in arced tracks that run anteriorly and posteriorly in the fixed, metal tibial component (see Figures A and D).

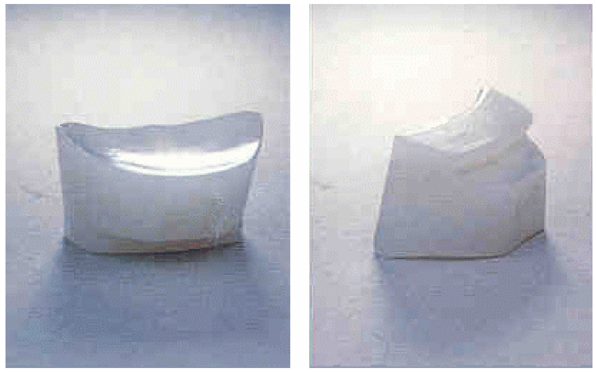

Figure A: Low Contact Stress (LCS) Meniscal Bearings
J&J DePuy – Warsaw, Indiana, USA

Unicondylar Meniscal Bearing: an implant in which only the medial or lateral compartment of the knee is replaced. The polyethylene may run in a track as described above, or may move freely, held in place only by its reciprocal shape and the tension of the surrounding ligaments (see Figure F).

- Type of Constraint (prevention of bearing dislocation):

  Cone-in-cone Design: incorporates a tapered projection of the polyethylene insert that inserts into a reciprocal concavity in the tibial tray (see Figure B).

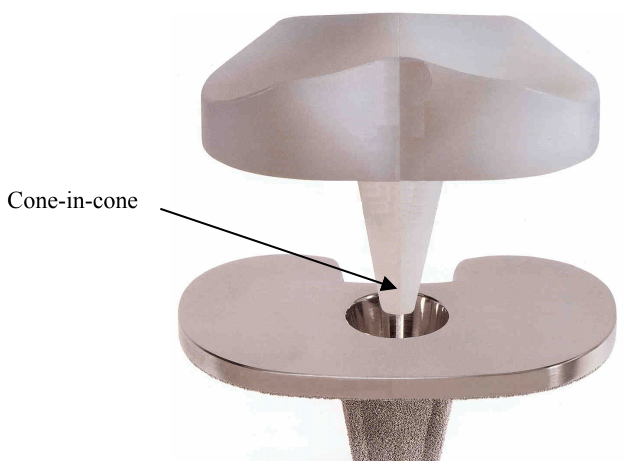

Figure B: Low Contact Stress (LCS) Rotating Platform
J&J DePuy – Warsaw, Indiana, USA

<u>Tibial Tray Post</u>**:** A post extending from the superior surface of the tibial tray fits into a recess on the polyethylene insert (see Figure C).

Tibial Tray Post

Figure C: Mobile Bearing Knee (MBK)
Zimmer – Warsaw, Indiana, USA

<u>Longitudinal Curved Sliding Tracks</u>**:** Movement of the platform or meniscus is limited by a track formed in the upper surface of the tibial tray (see Figure D).

Sliding tracks

Figure D: Low Contact Stress (LCS) Meniscal Bearing
J&J DePuy – Warsaw, Indiana, USA

Stops: elevated rim of the tibial tray that limits excessive A/P translation or rotation (see Figure E).

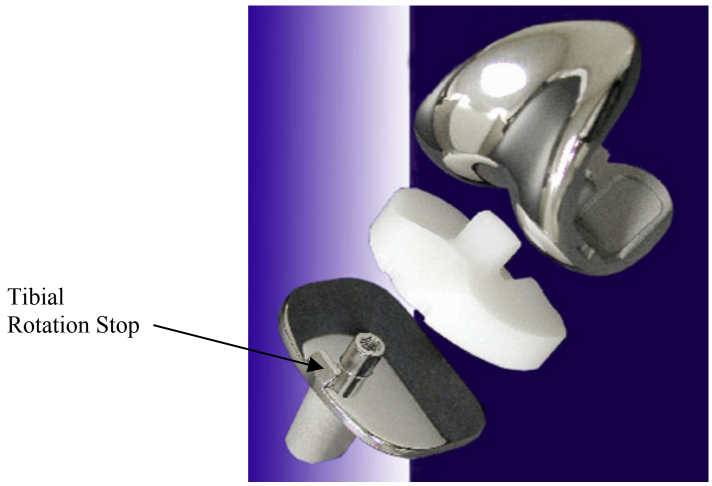

Figure E: LPS-Flex Mobile Knee
Zimmer – Warsaw, Indiana, USA

Unconstrained Bearing: designs that lack a mechanical limit to movement, but instead rely on the conformity of the polyethylene mobile bearing to the femoral condyle and the tension of the soft tissues (see Figure F).

Figure F: Oxford Unicompartmental Knee
Biomet – Bridgend UK

- Directional Mobility of the Bearing Surfaces:

  The mobile polyethylene bearing has been utilized in a variety of designs that permit mobility in one or more directions. Some have only rotational mobility, which permits internal and external movement in the transverse plane. Some have multidirectional mobility, which may include anterior/posterior (A/P) and medial/lateral (M/L) movement in addition to rotational mobility. The amount of mobility permitted by a number of designs of mobile bearing knees has been evaluated.[69] Nine knee designs were tested in a dynamic testing system in which compressive load was applied as the knee was rotated or moved in the A/P or M/L direction. Torque or shear forces were measured and plotted against displacement, thus characterizing the ability of the knee design to constrain displacement during gait. The nine designs were then characterized as "unconstrained", "semi-constrained", and "constrained". *Unconstrained* are those designs characterized by very low constraint forces over the entire range of normal (physiologic) displacements. *Semi-constrained* are those that have near physiologic constraint that rises over the range of normal displacements. *Constrained* designs are characterized by constraint forces that exceed physiologic levels and rise sharply over the range of displacements. Of the nine designs evaluated, all demonstrated unconstrained motion in the rotational direction. Rotation in the transverse plane is a primary requirement of normal gait, and all the mobile bearing designs demonstrated unconstrained mobility within a total of 15 degrees internal/external rotation. Relative to M/L mobility, the designs tested were evenly divided between semi-constrained and constrained mobility. Constrained and semi-constrained M/L mobility is characteristic of both mobile and fixed bearing knee designs, and does not adversely affect clinical performance. Analysis of A/P mobility revealed a wide range of constraint, with unconstrained designs prevailing. In order to achieve joint stability with the lower level of constraint, competent soft tissue, including balanced collaterals and/or the PCL are necessary.

- Congruence:

  <u>Fully congruent</u> mobile bearing knees are those that have a high degree of conformity between the femoral condyle and the polyethylene bearing surface, over a wide range of flexion (approximately 120 degrees). The congruence is achieved over this range by providing a constant sagittal femoral radius. These prostheses have a theoretical range of flexion of 120 degrees, limited by posterior impingement of the tibial component[27]**.** A fully congruent prostheses has a large contact area between the femoral condyle and the bearing surface, which disperses contact forces. This can result in reduced polyethylene wear.

  <u>Gait congruent or partially congruent</u> mobile bearing knees have large contact areas in the first 20 degrees of flexion. The contact area decreases with flexion due to a decreasing sagittal radius. These prostheses maximize contact areas in

the more important low end of the flexion range, while decreasing the sagittal radius to improve flexion range[180].

Individual manufacturers may characterize the degree of congruence of their designs using alternate terminology. For example, the Scorpio designs (Stryker Howmedica Osteonics) are described as "functionally congruent", meaning that they have a single femoral radius for up to 75 degrees of flexion.

- PCL Management:

  Mobile bearing knees are available in PCL-retaining, PCL-sacrificing and PCL-stabilizing designs. In general, knees with only rotating mobility utilize a PCL-sacrificing or PCL-stabilizing design, while multidirectional platform knees generally are PCL-retaining.

In summary, there are numerous mobile bearing knee designs on the market worldwide that are designed with two common purposes. The first is to increase contact area in order to reduce long-term wear. The second is to reduce implant-to-bone interface stresses and allow good kinematics by allowing mobility of the polyethylene bearing on the tibial plate. The number of variations of design available is testimony to the intense interest in developing a mobile bearing alternative to traditional knees, and in the process, elevate the science of prosthetic knee development to the next level.

B. Specific Intended Use

Mobile Total Knee

This device is indicated for:

- Patients with knee pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders and/or 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
- The salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery

The device can be used with or without bone cement.

Mobile Unicompartmental Knee

This device is indicated for:

- Patients with knee pain and disability due to osteoarthritis or traumatic arthritis
- Previous tibial condyle or plateau fractures with loss of anatomy or function
- Varus or valgus deformities
- Use with an intact Anterior Cruciate Ligament (ACL)
- Revision of previous unicompartmental arthroplasty procedures

The device can be used with or without bone cement.