

**EXHIBIT 4**

12963255

**Summary of Safety and Effectiveness**

**Smith & Nephew Orthopaedics**

**JAN -2 1997**

**Profix Plus Tibial Insert**

The Profix Plus Tibial insert is designed to work with the Profix Knee System to provide for the option of rotational constraint. The tibial insert is a single use device. The Profix Knee System is for Cemented use only.

The Profix Plus Tibial Insert when used with the Profix Knee System is designed for patients with the following indications:

- 1) Rheumatoid arthritis
- 2) Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
- 3) Failed osteotomies, unicompartmental replacement, or total knee replacement.
- 4) Constrained Systems are designed for use in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e., medial collateral and/or lateral collateral ligament) are absent or incompetent.

The Profix Plus Tibial Insert is also indicated for use where a knee cannot be stabilized by soft tissue release. The Profix Plus Tibial Insert is part of a system that is indicated for use only with cement and is a single use device.

This device has been tested and produced acceptable results that indicate that the product should perform well.

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