

# **Multi-center, open label, prospective, consecutive series registry database of BioPoly™- RS Partial Resurfacing Knee Implant**

## **Inclusion Criteria:**

Subjects **will be considered** for the clinical study if, at the first consultation, they are found to have:

- Age 21 years and older
- Cartilage lesion(s) located in the weight bearing region of the medial or lateral femoral condyles that have failed prior therapy (conservative or surgical)
- Symptomatic lesions classified as ICRS grade 2, 3, or 4
- Lesion size may not exceed 3.1 cm<sup>2</sup> and must be circumscribed by a 1.0, 1.5, 2.0 cm circle or 1.5 cm (M-L) by 2.4 cm (A-P) oval of normal or nearly normal (ICRS Grade 0 or 1) cartilage, with an overall depth less than 4 mm from the articulating surface
- Subchondral bone quality sufficient to support the implant
- Understanding and willingness to comply with the post-operative rehabilitation instructions and follow-up visits

## **Exclusion Criteria:**

Subjects **will not be considered** for the clinical study if, at the first consultation, they are found to have:

- Body mass index (BMI)  $\geq 30$
- Generalized degenerative or autoimmune arthritis.
- Gout
- Any concomitant painful or disabling disease of the spine, hips, or lower limbs that would interfere with evaluation of the afflicted knee.
- Uncorrected chronic malalignment of the knee (may be corrected at the same time as the implantation of the BioPoly device).
- Uncorrected ligamentous instability (may be corrected at the same time as the implantation of the BioPoly device).
- Uncorrected mechanically symptomatic meniscal tear or total meniscectomy (may be corrected at the same time as the implantation of the BioPoly device).
- Kissing lesion on tibia
- More than one implant required to accommodate lesion
- Allergy to titanium alloy (Ti-6Al-4V), ultra-high molecular weight polyethylene (UHMWPE), or hyaluronan/ hyaluronic acid (HA)
- Pregnant, prisoner, smoker, drug abuser, workers' compensation recipient, HIV or acquired AIDS