

BioPoly® Partial Resurfacing Knee Implant IDE

NCT06915363

Status	RECRUITING
Phase	Not Applicable
Sponsor	BioPoly LLC
Enrollment	152 participants

Key Eligibility Criteria

Inclusion (8)

- Patient is between 30 and 65 years of age.
 - KOOS quality of life score \geq 60.
 - In the opinion of the Investigator, the patient has the understanding and willingness to comply with all study requirements including the Post-Operative rehabilitation and follow-up protocol.
 - Patient has cartilage lesion that has failed non-surgical conservative therapy (e.g, anti-inflammatory (NSAID), viscosupplementation, steroid injection, physical therapy, or activity modification) after at least 2 months of beginning the therapy or failed surgical conservative therapy (e.g. debridement/lavage, marrow stimulation, or alignment high tibial osteotomy) that was performed at least 12 months ago in the index knee and is a candidate for surgical intervention.
 - Patient has cartilage lesion located in the femoral condyle or trochlear facet.
- ... and 3 more (see full listing online)

Exclusion (26)

- Patient has body mass index (BMI) \geq 35.
 - Patient has autoimmune arthritis, as diagnosed by Investigator.
 - Patient has advanced degenerative osteoarthritis in index knee (Kellgren-Lawrence Grade 4 and/or diagnosed intraoperatively).
 - Contralateral knee is known to have symptomatic cartilage, meniscal, or ligamentous lesions, generalized osteoarthritis, or requires surgery.
 - Patient has gout, by Investigator diagnosis or patient-reported history within last 12 months.
- ... and 21 more (see full listing online)

Locations (1 total)

Dupont Hospital, Fort Wayne, Indiana, United States