

The Hyalex Early Feasibility Study (EFS)

NCT06368700

Status	RECRUITING
Phase	Not Applicable
Sponsor	Hyalex Orthopaedics, Inc.
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (14)

- years.
 - Body Mass Index (BMI) \leq 38.
 - Singular treatable joint surface lesion, ICRS Grade 3 or 4, located on the medial or lateral femoral condyle.
 - One implant to treat a single symptomatic lesion with up to 3.8cm² total lesion area.
 - Knee Injury and Osteoarthritis Outcome Score (KOOS) pain subscale score between 20 and 65.
- ... and 9 more (see full listing online)

Exclusion (22)

- HYALEX Implant, Surgical Technique, and Lesion Site Exclusions:
 - Known allergy to polyurethanes, bone cement, acrylic, or titanium.
 - Lack of 2mm of healthy cartilage (ICRS Grade 0 to 2) and 2mm of vital bone wall on all sides of the implant site.
 - Osteochondral defect affecting subchondral bone more than 11mm in depth from adjacent non-defect articular surface.
 - Bipolar cartilage lesions involving patellar or tibial lesions ICRS Grade 3 - 4 opposite the lesion intended for treatment.
- ... and 17 more (see full listing online)

Locations (4 total)

Horizon Clinical Research, La Mesa, California, United States
Ochsner Sports Medicine Institute, New Orleans, Louisiana, United States
Hospital for Special Surgery, New York, New York, United States
... and 1 more locations