

The Hyalex First-in-Human Study

NCT06344481

Status	RECRUITING
Phase	Not Applicable
Sponsor	Hyalex Orthopaedics, Inc.
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (14)

- years.
 - Body Mass Index (BMI) \leq 35.
 - Singular treatable joint surface lesion, ICRS Grade 3 or 4, located on the medial or lateral femoral condyle.
 - Symptomatic, single treatable area 1 - 3.8cm².
 - Knee Injury and Osteoarthritis Outcome Score (KOOS) pain subscale score between 20 and 65.
- ... and 9 more (see full listing online)

Exclusion (24)

- 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 or 1) 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 19 more (see full listing online)

Locations (2 total)

SPORTO, Lodz, Poland
LIFE Medical Center, Warsaw, Poland