



Agili-C™

Inclusion Criteria

01. 21-75 years
02. Up to 3 treatable joint surface lesions, ICRS Grade IIIa or above, on the femoral condyles or trochlea
03. Symptomatic total treatable area 1-7 cm². Asymptomatic lesions will not be included in the calculation
04. Must be physically and mentally willing and able to comply with the post-operative rehabilitation protocol and scheduled clinical and radiographic visits
05. Signed and dated the IRB/Ethics Committee approved Informed Consent Form and HIPPA, if applicable
06. Non-responsive to physical therapy for at least 3-4 weeks

Exclusion Criteria

01. KOOS Pain subscale score at baseline is less than 20 or more than 65 (scale: maximum pain=0, pain free=100)
02. Bony defect depth deeper than 8mm, according to baseline MRI/X-ray/arthroscopy
03. Articular cartilage lesions in the tibia or the patella, ICRS grade IVa or above
04. Osteoarthritis of the index knee graded 4 according to the Kellgren-Lawrence Grading
05. Significant instability of the index knee according to IKDC Knee Examination Form 2000, Grade C (abnormal) or D (severely abnormal)
06. Malalignment more than 8 degrees varus OR 8 degrees valgus according to standing X-ray
07. Lack of functional remaining meniscus, at least 5mm rim, at the end of the procedure
08. Meniscal transplantation in the past 6 months
09. Any known tumor of the index knee
10. Any known history of intra-articular or osseous infection of the index knee
11. Any evidence of active infection anywhere in the body. Urinary Tract Infection (UTI) patients can be included following antibiotic treatment, and provided that two consecutive cultures are negative (taken within at least 2 weeks of each other)
12. Any known history of inflammatory arthropathy or crystal-deposition arthropathy
13. Any known systemic cartilage and/or bone disorder, such as, but not limited to, osteoporosis, chondrodysplasia or osteogenesis imperfecta
14. BMI > 35
15. Chemotherapy in the past 12 months
16. Any previous surgical cartilage treatment (such as: microfracture, ACL, OATS, etc.) in the index knee within the last 6 months
17. Any previous ligamentous repair or malalignment correction in the index knee in the last 6 months
18. History of allergic reaction or intolerance of materials containing calcium carbonate or hyaluronate
19. Patient who is pregnant or intends to become pregnant during the study
20. History of any significant systemic disease, such as, but not limited to, HIV, hepatitis, HTLV, syphilis, and coagulopathies
21. Known substance or alcohol abuse
22. Participation in other clinical trials within 60 days prior to the study or concurrent with the study
23. Known insulin dependent diabetes mellitus
24. Unable to undergo either MRI or X-ray
25. Use of anticoagulation medication or antiaggregant medication; however, up to 100 mg Acetylsalicylic acid (ASA) daily is allowed
26. Previous intra-articular steroid injection within the last 1 month
27. Prisoners
28. Uncontained lesion - Lack of vital bone wall, at least 2mm thick, completely surrounding the lesion, based on MRI/X-ray/arthroscopy
29. Inability to position the implant 2mm recessed relative to the articular surface, based on MRI/X-ray/arthroscopy