

CARTIGROW

Treatment Guide for Cartilage Cell Therapy

CARTIGROW® Treatment Guide for Cartilage Cell Therapy

www.regrow.in

Thank you for being a part of **CARTIGROW**® Cartilage Cell Therapy. To ensure every patient undergoing the treatment is safe and gets the maximum benefits, we recommend the following steps for achieving a satisfactory clinical outcome.



CARTIGROW® is covered under cashless reimbursement schemes from all major Private/Central Government and State Health Insurance Schemes.

CARTIGROW® Cartilage Cell Therapy has proven its safety and efficacy in clinical trials and Post Marketing Surveillance studies in India. According to the clinical data analysis, most of the patients with Cartilage Damage of articulating joints (e.g. Knee) qualify for treatment with **CARTIGROW**®, however, every Cartilage Damage patient may not be eligible. Therefore, it is essential to identify suitable patients for the treatment.



1A. ASSESSMENT OF CLINICAL HISTORY AND CURRENT MEDICAL CONDITIONS

The articular cartilage lining the bones helps with smooth movement. If it's torn or worn, it can leave the rough bone surfaces exposed – resulting in friction in the joint. Damaged cartilage can lead to knee arthritis, with long-term effects on the knee function. Hence, checking the patient's medical history is crucial for better clinical understanding and prognosis. Do take note of the patient's concomitant medication and comorbidities, if any. Do ensure the patient is currently NOT associated with any of the following:

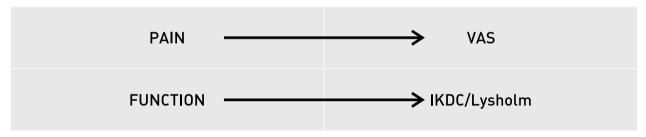
- On-going chemotherapy/radiation treatment
- Undergone participation in any Clinical Trials in the last 1 year
- × Previously undergone organ or bone marrow transplant in the last 6 months
- regnancy, breast-feeding or having a positive pregnancy test before receiving the therapy

- ✗ Patients on wheelchairs (autophagic or paraplegic)
- ➤ Patients aged below 18 years shall not be considered
- × Degenerative joint changes due to osteoarthritis and rheumatoid arthritis

1B. STAGING OF CARTILAGE DAMAGE

- Confirm the Stage of Cartilage Damage: Magnetic Resonance Imaging (MRI) can be used to determine the Stage and Extent of Cartilage Damage
 - o CARTIGROW® is applicable for ICRS stages (Stage 1 4)
- O Suggested capture of patient's pain and functional scores to understand their baseline levels

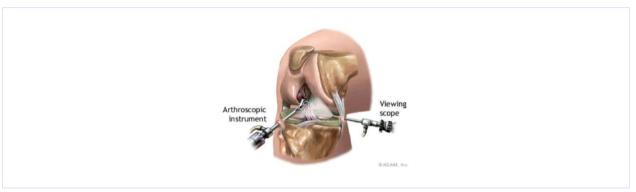
PAIN & FUNCTIONAL SCORING



VAS- Visual Analogue Score
VAS score should decrease with treatment

IKDC - International Knee DocumentationCommittee/Lysholm

IKCD / Lysholm score should increase after treatment



2A. CARTILAGE TISSUE HARVEST (CTH)

CTH is the first step of the treatment procedure. A CARTIGROW $^{\circ}$ CTH Transport Kit will be sent to the hospital in cold chain on or before the assigned date of the procedure.

Once the CTH process is complete, Regrow's trained paramedical staff will carry this kit to the Regrow GMP lab for further steps. Refer to CTH Manual <u>here</u> for detailed treatment procedure.

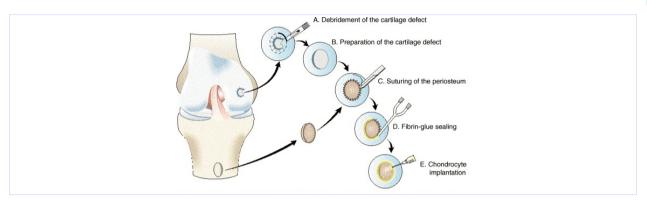
- Refer to the CTH manual for step by step guidance
- o 🕓 our team for more information as required



2B. REGROW CELL CULTURE

Once the CTH procedure is complete, the CTH Transport kit will be collected by our team and transported to Regrow's Cell Processing Centre located in Lonavala, Maharashtra. The cells will be cultured in Regrow's GMP facility for approximately 4 weeks.

- Regrow® Operations Team will update you regarding the quantity/quality of the cell yield within the first 10 days upon receipt of the Transport Kit
- In case the initial cell yield is unfavorable, we may advise you to repeat the CTH procedure. However, the chances of this are below 3%din!!
- Once the cells are successfully cultured beyond a certain phase, the team will coordinate with you and the patient to fix the suitable cell implantation date and time



2C. FINAL PRODUCT IMPLANTATION

Implantation is the last step of the treatment procedure.

The **CARTIGROW**® Delivery Kit will be sent to the hospital in cold chain on the assigned date of the procedure along with Regrow's trained paramedic staff. Before performing the implant, please Refer to the <u>Implantation manual</u> for a step by step guidance.

Educate the patient about the post-treatment care and rehabilitation program. Since each patient's program would be customized basis their medical condition and needs, **Regrow**® has prepared an **CARTIGROW**® Treatment-related <u>Rehabilitation Manual</u>.

STEP 3- FOLLOW-UP OF THE PATIENT



Follow-up of the patients is crucial to determine their safety, disease progression, and benefit of the overall treatment provided.

Suggested PROM (Patient Related Outcome Measure Score) and Radiology Assessment is mentioned below with their respective timelines:



We would like to take this opportunity to inform you that Regrow® has prepared a "Patient Pack" that includes:

- Product Flyer, Surgery Prep Guide, and a Rehabilitation Manual
- If you would like to receive the Patient Packs, do let us know, and we will gladly provide them at your clinic or hospital premises
- For more information, visit: www.regrow.in

CARTIGROW® CARTILAGE CELL THERAPY PUBLICATIONS

- 1. Gel-Based Autologous Chondrocyte Implantation (GACI) in the Knee Multicentric Short Term Study
- 2. Gel Based Autologous Chondrocyte Implantation The Surgical Technique
- 3. Efficacy and safety of CARTIGROW® in patients with articular cartilage defects of the knee joint a four-year prospective study

Please Reach Out To Us:



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THANK YOU!