

A man in an orange t-shirt and black shorts is performing a lunge stretch on a concrete pier. He is looking off to the side with a slight smile. The background shows a body of water and a railing under a bright sky.

CARTIGROW[®]

CARTILAGE CELL THERAPY

WELCOME!

Thank you for picking up this book about **CARTIGROW**[®] cartilage cell therapy. It is a privilege for us to be your partner during this time. Our goal is to outshine your expectations in every interaction with our healthcare team.

The ultimate objectives of our services are to provide pain relief, improve joint motion, and support you to get back to your everyday activities. This guide is created keeping you and your needs in mind by using insights from our patients and families. It contains details that they felt were most important and helpful while receiving care. We hope you find it useful for preparing and receiving care at this facility. If you have any special requests or concerns during your stay, please tell your nurse or any member of your care team so that we can work to meet your needs. This guide is intended to supplement the information and advice you receive from your doctors; it does NOT take the place of a discussion with your surgeon.

This guide contains information about Regrow Biosciences **CARTIGROW**[®] cartilage cell therapy. As per your needs, you may refer to the specific sections. You can use the Notes section in this guide to take down important points. Some words may be new to you. See the Health terms section in this book or call your doctor for clarification.

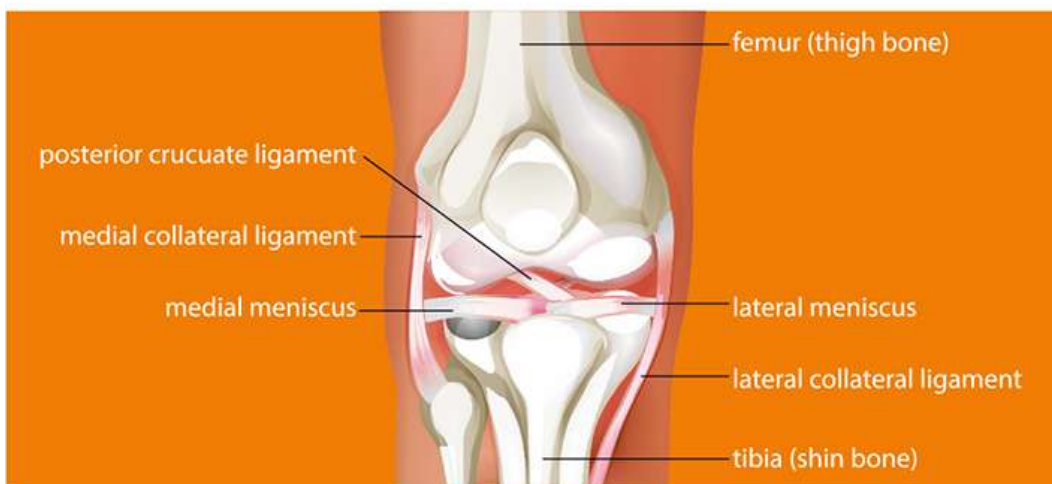
About your knee

The knee joint is one of the strongest and most important joints in the human body. It allows the lower leg to move relative to the thigh while supporting the body's weight. Movements at the knee joint are essential to many everyday activities, including walking, running, sitting, and standing.

The knee joint connects the thigh bone (femur) and the shin bone (tibia). The knee can be thought of as a simple hinge-type joint permitting you to extend (straighten) and flex (bend) your knee. The actual movements of the knee are more complex and include rolling, pivoting, and small rotations on either side.

Articular cartilage

Similar to other joints, smooth articular cartilage covers the ends of these bones; uniquely in the knee, cartilaginous disks called menisci further cushion and protect the knee. The combination of the articular cartilage and the menisci permits the knee bones to glide smoothly and effortlessly through the motions of standing, sitting, jumping, running, and taking stairs. Taking stairs and running, for example, can exert 5-7 times your body weight on the knee joint.



HUMAN KNEE ANATOMY

Source: freepik.com

Types of cartilage:

- **HYALINE CARTILAGE:** Present in all major joints like knee, hip, shoulder, and ankle. It absorbs shocks and bears weight. If damaged, it leads to fibrous cartilage growth.
- **FIBROUS CARTILAGE:** Very weak in strength, has a glass-like appearance, and is brittle.

What happens when the articular Cartilage is damaged?

Damage to the articular cartilage is caused by wear-and-tear of the cartilage at the end of the bones. As the cartilage wears away, the bone ends rub against each other causing grinding, accompanied by pain and swelling. As the damage progresses, there may be swelling around the knee, tenderness, stiffness, and pain with the inability to straighten the knee. In severe cases, the knee may appear deformed with knock-knee or bow-legged deformities.

SIGNS OF CARTILAGE DAMAGE:



Pain and swelling in joint(s)



"Clicking" sound from joints



Stiff joint(s) and sometimes locked joint(s)



Restricted movement of joint



Difficulty in walking or climbing the stairs



Extreme pain while playing sports

How does **CARTIGROW**[®] Cartilage Cell Therapy work?

● **STEP 1: CARTILAGE TISSUE BIOPSY**

You heal your own cartilage. Cartilage Tissue Biopsy is a simple day-care procedure involving the extraction (biopsy) of a small quantity (4-5 mm) of your healthy cartilage tissue from an extra (non-weight bearing) portion of the knee. The procedure lasts for 15-30 minutes. You will be given local or general anaesthesia. This is aseptically transported to a centralized GMP certified cell culture laboratory. Cartilage forming cells- chondrocytes- are cultured within 21-25 days.

● **STEP 2: CARTILAGE TISSUE IMPLANTATION**

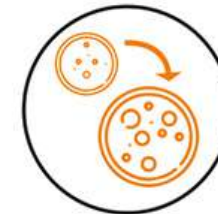
The cultured cells (in millions) are implanted onto the damaged area of your knee under local or general anaesthesia. You can return to your home as early as two days after this step.

It is encouraged to NOT keep your minor daily activities on hold after surgery to allow a quick formation of cartilage cells. Through constantly guided physiotherapy including muscle strengthening and load-bearing capacity exercises, the newly formed cartilage tissue becomes mechanically robust allowing all activities including professional sports overtime.

TREATMENT PROCEDURE



Extraction of healthy cartilage tissue



Cartilage tissue culture



Implantation of cultured cartilage tissue

SUCCESS OF CARTIGROW[®]

Clinical studies in India involving Cartilage Cell Therapy have a success rate of up to 95%.

- Patients were pain-free and did not require any further treatments. No product-related safety issues were reported
- **CARTIGROW**[®] Cartilage Cell Therapy (Manufactured by **Regrow Biosciences**[®] Pvt. Ltd.), is approved for treating articular cartilage defects by the Drugs Controller General of India (Central Drugs Standard Control Organization), Ministry of Health and Family Welfare, Govt of India
- Ability to restart sports by 6 months
- More than 80% pain reduction within 2-4 months
- More than 5X improvement in physical activities



Preparing for cell therapy

You have taken the first step to save your joint. To ensure everything is carried out smoothly, you will undergo a checkup to make sure you are healthy for the procedure. To find out if you are a good candidate for the procedure, the doctor will consider:

- ✓ Your general health
- ✓ Your medical history
- ✓ Type and stage of the disease
- ✓ Results of physical check-ups and medical tests
- ✓ Psychological assessment/ mental fitness

When you have successfully cleared all the checkpoints, the doctor will give you further instructions and suggestions.

Before surgery, your healthcare team will review the medical records and may order certain lab tests or studies to ensure that you are in the best possible condition. The team will make sure everything is well prepared for the treatment.

It may be useful to consider the following points:

- Complete any dental treatments
- Find someone who can take care of your pet
- If you have children or are a single parent, arrange for someone to look after, while you are away

- Complete any personal/ work trips

Regrow Biosciences® services are covered under cashless and reimbursement schemes for all major Private/ Government and State Health Insurance Schemes. For further information, please contact Regrow at **1800-209-0309** or put in an inquiry on the official website (www.regrow.in) or the Facebook page.



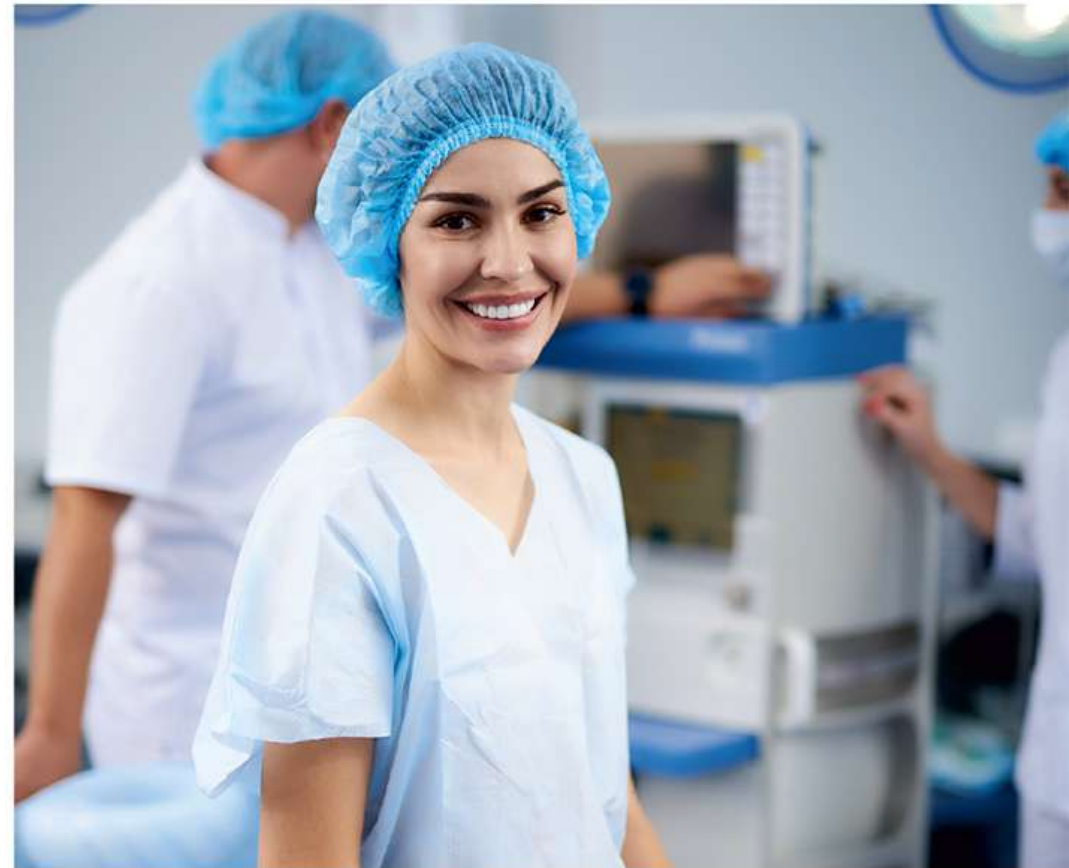
One month before the treatment

Medical tests

Medical tests are important for the preparation of the treatment. They are useful in the diagnosis of the treatment and to make sure you are healthy enough for the treatment. Some tests may include:

- **X-Ray:** An X-Ray can help doctors diagnose, monitor, and treat many medical conditions. In most cases, you won't need to take special steps to prepare for them. You may want to wear loose, comfortable clothing that you can easily move around in. They may also ask you to remove any jewelry or other metallic items from your body before your X-Ray is taken.
- **Magnetic resonance imaging (MRI):** An MRI is a type of scan that uses magnetic fields and radio waves to produce detailed images of the parts inside of the body. An MRI scanner is a large tube that contains powerful magnets. You will have to lie inside this tube. Before the test, you can eat normally and continue to take your usual medications, unless otherwise instructed. They may also ask you to remove any jewelry or other metallic items from your body before your test.
- **Urine tests:** It is useful for detecting and managing a wide range of

bodily functions. This test is also beneficial for ruling out pregnancy for women of childbearing potential.



Get yourself a caregiver

Ideal caregivers can be your spouse, sibling, partner, parent, adult child, or any close friend. Having a caregiver is very helpful. Patients who undergo the treatment need an adult caregiver to provide support and care. He/she should be with you at all times especially after you are discharged from the hospital. The caregiver can help get the home environment ready before the treatment and help attend appointments. Members of your healthcare team will instruct the caregiver on the necessary roles and responsibilities to support you. You may also avail at-home nurse service according to their convenience.

When you return home, your caregiver can help you with the following:

- Ensure that you take any medication at proper times.
- Monitor your health and report any new symptoms to the doctor or his team
- Clean the house to ensure hygiene is maintained at all times.
- Cook proper healthy meals
- Assist with daily activities. No matter how big or small the task may be
- Assist financially and ensure bills are paid on time
- Provide emotional support to keep track of your mental health



Eat Right

Adequate nutrition is important for overall good health and also for preparation for the treatment and healing after. If you do not have proper protein, vitamin, and mineral intake, you are more likely to have post-operative problems. A well-balanced and nutritional meal before and after treatment can help in a better overall outcome.

EAT ENOUGH PROTEIN. Protein provides building blocks for our muscles, bones, and immune system. You want to be as strong as possible going into the treatment.

STOCK UP ON FRUIT AND VEGETABLES. Include fruit and vegetables at most meals and snacks. More specifically, greens. Greens are great for your skin and repair muscles, bones, and cartilage because they contain loads of vitamins and minerals including vitamins C, K, and magnesium.

INCLUDE WHOLE GRAINS. Be sure to include good sources of whole grains to give your body all the B vitamins it needs to combat stress.

Eat less of these

Consider reducing or eliminating additional sugars, caffeine, and alcohol from your diet. These create more stress on the body and remove nutrients from the body to metabolize properly.



Just before you begin the treatment

WHAT TO EAT?

You will be given local or general anaesthesia before the collection of cells. Some patients react to anaesthesia by vomiting. This is not favorable and can be dangerous. Your stomach must be empty so nothing is expelled from your mouth or into your lungs. You must not eat or drink anything - **NOT EVEN WATER** - certain hours before the surgery. If you eat or drink anything, your treatment may be postponed. The only exception is for medications, taken only with the doctor's approval.

We realize you may need medications for other conditions and we want to make sure you are safe during your surgery. Make sure you inform your doctor before you decide to take any medication. Your doctor and his team will review your medications and decide if you should be allowed to take anything before your surgery or if it would be safer to wait until a few days.

You may consider the following:

- Plan to arrive two hours before the appointment time.
- Leave money and other valuable items at home or with your caregiver.
- If you wear hearing aids, glasses, dentures, or contact lenses, please bring them with the containers.

- Make a list of all your allergies and any ongoing medications you are on, and also the last time you took a dose.

Kindly do not carry any medications with you.



DAY OF TISSUE BIOPSY- STEP 1

After Arriving at the hospital

Meet the team

When you arrive at the hospital you will be greeted by a nurse and a nursing assistant will care for you. They are well trained to care for patients who have had similar procedures. The unit's physical therapist may also come in to discuss your rehabilitation plan and to start your therapy soon after your arrival.

Nursing care

Your nurses will be monitoring your vital signs (blood pressure, breathing, temperature, and heart rate), as well as your circulation to your leg. They will report to your doctor any abnormal findings. In the beginning, the nurses will do a complete assessment of your whole body, looking for anything that would delay your progress.

Communication with the staff

Good communication between patients and caregivers is important. We will discuss your goals for the day and talk about your recovery, your

therapy, and your discharge planning. The nurse will discuss your pain management and when your next dose of medication is due.

You may also use a call button to communicate your needs. The hospital staff will answer your call as quickly as possible. They will also follow up with a call to make sure your needs are addressed. If you have questions, you may have your nurse write them down, and of course, you may also write questions in this book.

Waiting room

You will be directed to a room to prepare you for the procedure. A family member or your caregiver may accompany you to the waiting room. You will be given a hospital gown to change into. You may give your clothes to the caregiver to hold for you. If privacy is needed, you may ask the person to step out of the room before you change.

You will be transferred to the operating room by a registered nurse or an orderly, who will stay with you throughout. The room will be cool and somewhat noisy. The noise is caused by the laminar flow fans, which will help keep the room sterile. You will be given local or general anesthesia. This step may take about 15 minutes.

Instructions for the caregiver

It is best if your caregiver can help you check-in. If your caregiver is planning to meet you at the hospital, give his/her name to the receptionist. Please have him/her check-in after his/her arrival at the hospital. After surgery, the caregiver will be contacted by the doctor to let him/her know how things went and when to expect you out of the room.

After Step 1, there would be a gap of about 3-4 weeks before cartilage tissue implantation, make sure you are having enough rest and adequate nutrition. You may carry out regular physical activities in moderation.



DAY OF TISSUE IMPLANTATION - STEP 2

The instructions remain the same as your first visit. However, on your second visit, you will be admitted for several days considering your overall health considerations.

Post implant period

After the procedure, you will be transferred to the post-anesthesia care unit (PACU) where you will be closely monitored. Your doctor will contact your family/caregiver(s) in the surgery waiting area to discuss your surgery and your condition. After your surgery, you may be a little thirsty or may feel a little sick. Some patients may experience nausea for a while. This usually fades after a while. There is a medicine that helps alleviate those symptoms. Please let your nurse know if you are feeling nauseated or have any signs of discomfort. They will do everything they can to make you feel more comfortable.

Pain management:

Your nurse and other staff will be available for your assistance if you feel any discomfort. It is normal to experience pain after the procedure. We will try our best to make you comfortable.

Ways you can help relieve your pain:

- Don't try to tough it out. Let your nurse know you have pain
- Understand that oral medication takes about 30 minutes to work, so don't wait for your pain to rise to the upper level of the pain tool before saying something to your nurse
- Even if you have a low amount of pain, remember you will tolerate your therapy sessions better if you are properly medicated
- Remember to call for help when walking and getting out of bed

While on the medication you have an increased risk of falling. We recognize that before surgery you might not have needed assistance, but now you must take precautions to be safe.

PLEASE CALL FOR HELP BEFORE ANY PHYSICAL ACTIVITY.

It is normal to have some joint pain swelling immediately after therapy. Ice may be applied to your joint for comfort, to help reduce this swelling, and to decrease your pain. Your nurse, doctor, and pharmacist will work together for the best pain control plan.

Notify your doctor immediately if you develop any of the above signs.

WARNING SIGNS

- Persistent fever (higher than or 38°C / 101°F)
- Shaking chills
- Increasing pain with both activity and rest



PREVENTIVE MEASURES

Prevention of falls

After the procedure, your risk of falling is high. We do not want you to trip and fall. Please use your call light to request help to get out of bed at all times during your hospital stay.

Bowel elimination

As a side effect of the pain medication and decreased activity, you may have constipation. We will encourage you to drink plenty of liquids, give you stool softeners, and teach you about foods that have a higher fiber to ease bowel elimination with less strain. If constipation continues to be a problem, there are other remedies to help, and we will discuss these options with you.



DISCHARGE FROM HOSPITAL

You will be ready for discharge from the hospital when:

- There are no signs of infection
- Medications (if any) are tolerable
- You can eat and drink without any discomfort
- You are physically able to function outside the hospital with some assistance

Your caregiver should contact the hospital immediately if the following symptoms are seen:

- Fever/chills
- Coughing, sneezing, runny nose, sore throat, shortness of breath
- Vomiting and nausea
- Blood in urine or discomfort in urination
- Rash or cold sores
- Oozing blood from the operated site
- Excessive amount of drainage from the dressing
- Severe pain in the limb joint/limb

Planning for discharge

You need to be prepared for going home. We believe a good plan for this starts from the very beginning of your treatment and continues through your hospital stay. Your doctor will recommend appropriate equipment (e.g., walkers, canes, commodes) and the course of follow-up therapy. Your nurse will provide you with written discharge instructions and information regarding your next doctor's appointment, medication, and incision care. The nurse also will go over your recovery plan.

Final discharge instructions from your nurse will include:

- Prescriptions for discharge medications
- Availability of your equipment
- Reasons to contact your physician
- Follow-up appointment with your physician
- Follow-up appointment with the lab for close monitoring of your blood

The hospital transport team will assist you during the discharge procedure.

After the discharge, more than one follow-up appointment with the doctor may be needed. During these visits, doctors will analyze blood test reports. As patients regain more strength, daily activities can be resumed. The recovery time is different for each person. On average, it takes around 1-2 months.

When to call your doctor

Call your doctor if you experience any of the following:

- Chest pain and/or shortness of breath
- Call 1-0-2 for ambulance service or go to the hospital emergency room
- Increased pain or swelling at the operated site
- Drainage from your dressing
- Fever of 101 Fahrenheit or 38 Celsius
- Any unusual symptoms that you don't understand
- Wound opening



AFTER YOUR TREATMENT

Nutritional information

What to eat?

It is important to eat a well-balanced diet after cartilage cell therapy. Foods that are rich in proteins will help in this process. If you do not consume the necessary amount of protein and calories, the body will take energy from its muscles, causing further weakness and fatigue. Caregivers must consult the doctor if the food and drink intake are lacking, inappropriate, or even harmful.

Protein-rich food

Protein is important in the maintenance and repair of body tissue, especially wound healing. You get adequate protein by consuming milk and milk products, meat, poultry, fish, and eggs. Good vegetable protein sources include beans, legumes, soybeans, lentils, nuts, seeds, and peanut butter.

In case of a special diet

If you are on a special diet, such as diabetic, renal, cardiac, or texture-



modified diet, consult your health professionals regarding your nutrition plan. You may also ask your doctor to refer you for a nutrition consultation.

What if I have a poor appetite and am not eating well?

Eat small, frequent meals and snacks to ensure adequate nutrition. Make sure the meals are rich in protein and calories. You may also want to try over-the-counter oral supplements for additional nutrition.

Do I need vitamin supplements?

If you are eating a balanced diet and eating enough, most likely you are getting adequate nutrition from your diet. However, if you are not eating well, you may want to consider taking a multivitamin supplement. Please consult your doctor or dietitian.

Food Safety

Always prepare food on a clean surface, with clean hands and utensils. Be sure the food is well cooked. For your safety, raw or undercooked unpasteurized eggs (such as homemade eggnog or poached eggs) may

not be served at any time.



Exercise

After the treatment, many patients find exercise and physical activities like walking, riding a bicycle, and basic yoga help in alleviating fatigue and increasing energy levels.

Home safety checklist

- Be aware of uneven surfaces both inside and outside your home
- To avoid rushing to answer your telephone, use a mobile phone instead of landlines
- Provide a place for your pets to be kept while you are walking around the house
- Maintain adequate lighting in all areas. Use night lights
- Use a raised toilet seat or commode frame
- Be cautious with wet floors
- Select footwear that stays securely on your feet
- Use chairs with armrests or place a firm cushion or pillow on the seat of chairs
- Move frequently used items to shelves and counters that are easy to reach. This reduces unnecessary and unsafe reaching
- Prepare simple meals using the stove top or counter-level appliances to avoid bending. Make food ahead of time and store it in small containers for heating later
- Check your bed/mattress height. It may be necessary to raise the

height of the bed so that the top of the mattress will be at or above your knee level

Home safety strategies

- Make sure your home is set up to create a safe environment for recovery
- Rearrange furniture so it's easier to get around
- In the bathroom aids like a shower hose, a tub seat, and a raised toilet seat can help you stay safe
- Watch out for hazards like wet floors or uneven surfaces

LONG TERM CARE

Long-term follow-up care is important for ensuring your safety and well-being. It helps doctors monitor patients for disease effects or recurrence. You may talk to your doctors about how often to have follow-up visits. Ask the doctor what type of tests will be needed and how often the tests must be taken. Keep a record of your treatment including drugs so your doctor can follow up on long-term effects associated with your treatment.

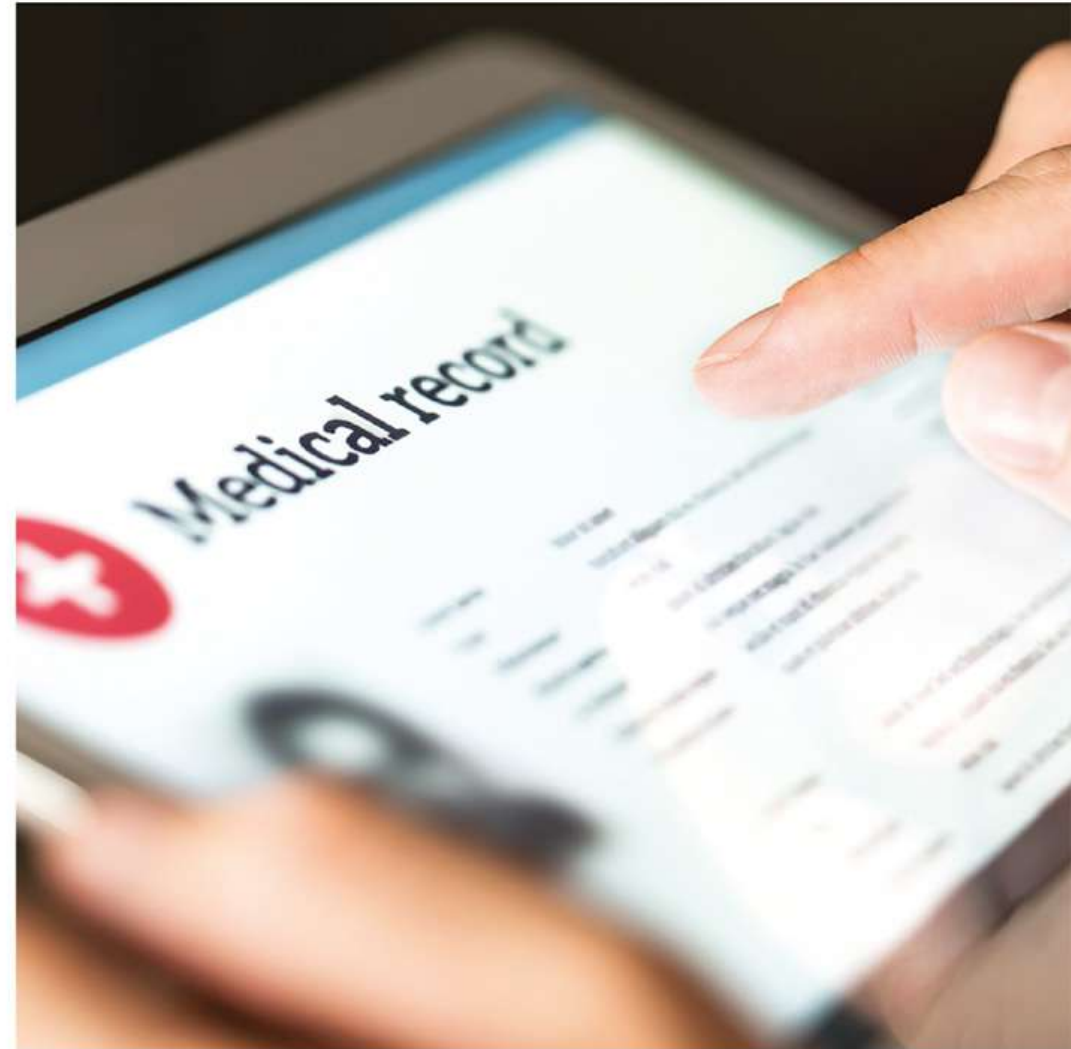
The doctor may advise longer periods between follow-up sessions if you are free from any signs of complications and concerns and do not need any additional medical care treatment for any long-term effects.



TAKE CARE OF YOURSELF

- Keep a record of all appointments with your doctor.
- Discuss how you feel at each visit. Ask any questions related to side effects.
- Eat healthy foods each day. You can eat 4 to 5 smaller meals instead of 3 bigger meals.
- Contact the doctor about tiredness, fever, or any other symptoms.
- Quit smoking and avoid alcohol. Get additional help if required.
- Get proper rest.
- Follow an exercise routine. Talk to your doctor before starting an exercise program.
- Maintain a proper healthcare file. Keep all the copies of lab reports and treatment records.
- Seek medical advice if you feel sad or depressed and your mood does not improve over time. Depression is a serious illness and it can be treated with proper support and advice.

If you are happy with the treatment, you may give a testimonial and spread the word.



FREQUENTLY ASKED QUESTIONS

- **How does CARTIGROW[®] help in the formation of new cartilage?**

In cartilage defects, the chondrocytes in the cartilage are damaged and do not repair themselves. Hence, when chondrocytes are injected into the damaged tissue, they develop a new and mature cartilage tissue.

- **Does the tissue formed with CARTIGROW[®] have the same strength as the original one?**

The tissue formed with CARTIGROW[®] restores the structure and function of the damaged joint and its strength. You can perform daily physical activities such as exercise and sports after treatment.

- **Who is an ideal candidate for CARTIGROW[®]?**

Patients with early to late-stage ICRS cartilage defects can be benefitted from CARTIGROW[®].

- **Is CARTIGROW[®] safe?**

Yes, safety and efficacy of CARTIGROW[®] have been proven through successful clinical trials in India. It is a DCGI approved biological and personalized drug, thus completely safe for administration in humans.

- **Is there any risk with CARTIGROW[®] treatment?**

As CARTIGROW[®] is an autologous (patient's own cell) cell therapy

product, no risk can be associated with it, such as GVHD (Graft vs. host disease), Graft rejection, and chances of infection. Thus, CARTIGROW[®] is a completely safe cell therapy product.

- **Is there a need to take other medications after CARTIGROW[®] therapy?**

There is no need to take any other medication after CARTIGROW[®].

- **Can CARTIGROW[®] be performed after previously failed procedures?**

Yes, upon detailed analysis and screening by the orthopedic surgeon, the patient may undergo CARTIGROW[®].

- **Is CARTIGROW[®] performed in India and where?**

Yes, CARTIGROW[®] is performed at all major private, government, and state hospitals across all cities in India.

- **What is the difference between knee Replacement and CARTIGROW[®] therapy?**

Knee Replacement is the process of replacing your original joint with an artificial implant (metal in most cases), whereas CARTIGROW[®] is a completely natural and safe procedure that involves the implantation of the patient's own cartilage cells.

- **What is the success rate of CARTIGROW[®]?**

The success rate of CARTIGROW[®] is more than 95%

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- ***Will I need more physical therapy?***

Yes, you will need to continue building and strengthening your affected joint. Your therapist will teach you exercises to practice to help you in your recovery.

- ***When can I travel?***

You may travel when you feel comfortable. It is a good idea to walk and stretch in between sitting positions to prevent blood clots.

- ***When can I expect to have a normal range of motion?***

Everyone heals at a different pace. You will be informed about different exercises that you can practice while in the hospital. The staff will help you practice your exercises, which will allow you to recover better and faster.

- ***Is this feeling of depression normal?***

It is not uncommon to have feelings of depression after any treatment, due to several reasons, such as limited mobility, discomfort, increased dependency on other people, and/or medication side effects. Typically, these feelings will fade as you return to your normal routine and activities. Seek professional advice or talk with your doctor if this concerns you.

- ***I can't get to sleep. Is this normal?***

This is a very common complaint. Some medications may be helpful. If you continue to have sleepless nights, please call your doctor for a prescription sleep aid.

HEALTH TERMS

- **CELL THERAPY:** Cell therapy is a therapy in which viable and healthy cells are injected, grafted, or implanted into a patient in order to effectuate a medicinal effect.
- **TISSUE:** Tissues are groups of cells that have a similar structure and act together to perform a specific function. Groups of tissues make up organs in the body such as the brain and heart.
- **AUTOLOGOUS CELLS:** Stem cells derived from the patient's own body.
- **ALLOGENEIC CELLS:** Stem cells collected from a donor and transplanted to the patient.
- **CARTILAGE:** A smooth substance in between two bones made up of specialized cartilage cells "chondrocytes", that helps in smooth joint movement.
- **PHYSIOTHERAPY:** The treatment of disease or injury by exercise, light, heat, rubbing the muscles (massage), etc.





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