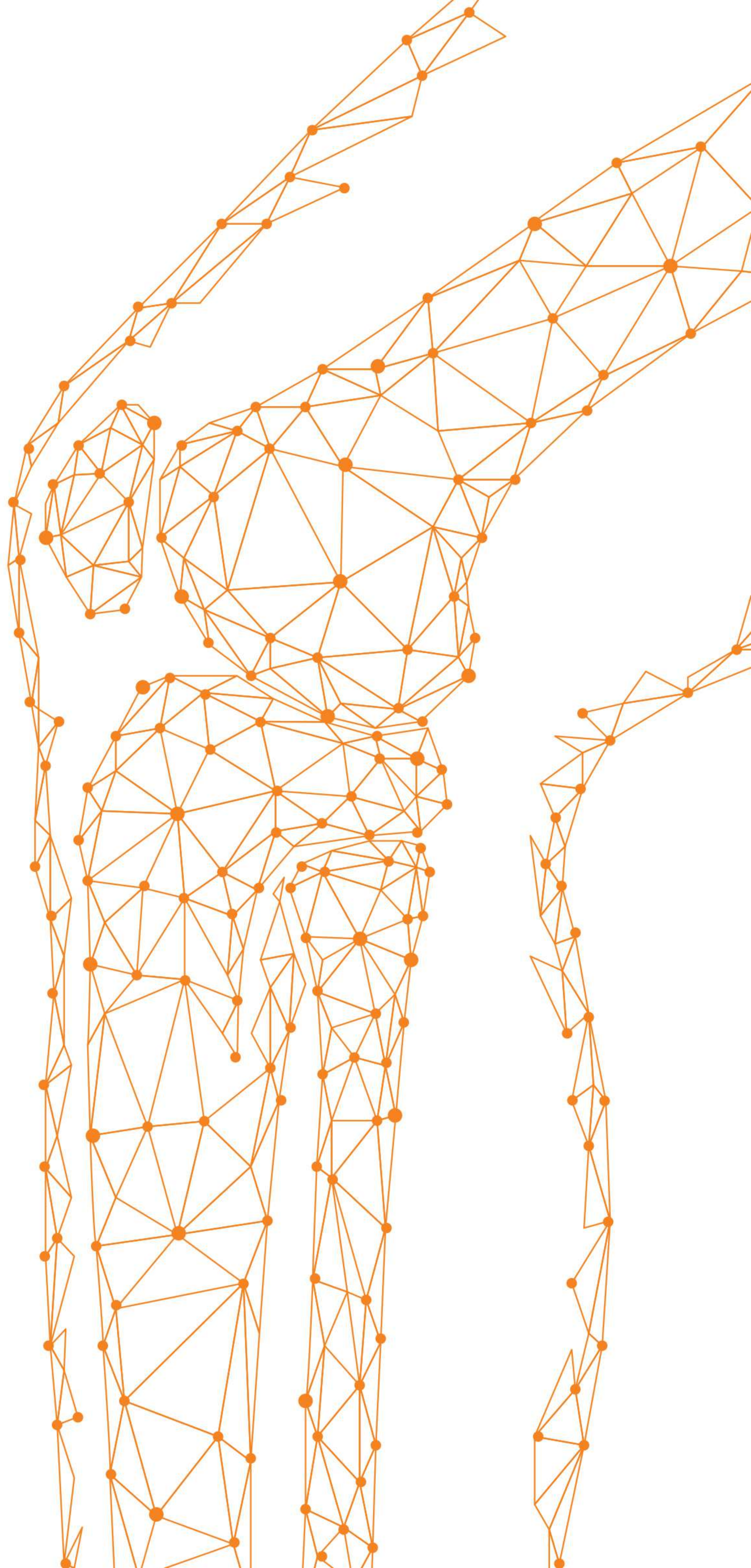


CARTIGROW®

IMPLANTATION

MANUAL





CARTIGROW®

CONTENTS

	Pg. No.
▶ CONTENTS OF PRODUCT BOX 2
▶ OTHER ASSISTING MATERIAL 3
▶ CONTENTS OF THE DELIVERY KIT 4
▶ PRECAUTIONS BEFORE IMPLANTATION 5
▶ POST IMPLANTATION PROCESS 8



CONTENTS OF THE PRODUCT BOX

1 - DELIVERY KIT

2 - 1ML SYRINGE(8 NOS)

3 - 20/21 GAUGE NEEDLE(8 NOS)

1



2



3



OTHER ASSISTING MATERIAL

1 - STERILE SCALE

2 - FDA APPROVED FIBRIN
GLUE KIT

3 - FIBRINOTHERM

1



2



3



CONTENTS OF THE DELIVERY KIT

- 1 - DELIVERY KIT (TO BE MAINTAINED AT 2°C – 8°C)
- 2 - OUTER VIALS (STERILE METAL CANISTER)
- 3 - INNER GLASS VIALS CONTAINING FINAL PRODUCT (STERILE) (MAX. UP TO 04 VIALS PER KNEE JOINT PER PATIENT)

FINAL PRODUCT (**CARTIGROW®**):

Over 12 million Autologous Adult Live Cultured Chondrocyte in 0.4ml DMEM solution



PRECAUTIONS BEFORE IMPLANTATION

Step wise instructions to be followed:

STEP 1

Just before implantation, place the Delivery Kit on non sterile trolley. Remove the Outer Vial(s) and place it on the same trolley.

STEP 2

Open the cap of metal canister. Take out the inner glass vial from metal canister with help of sterile gauze piece. Wipe the inner glass vial containing the final product and keep it on sterile trolley.

STEP 3

If media of inner vial is cloudy or showing any foreign particles, do not use the vial, instead use new vial.

STEP 4

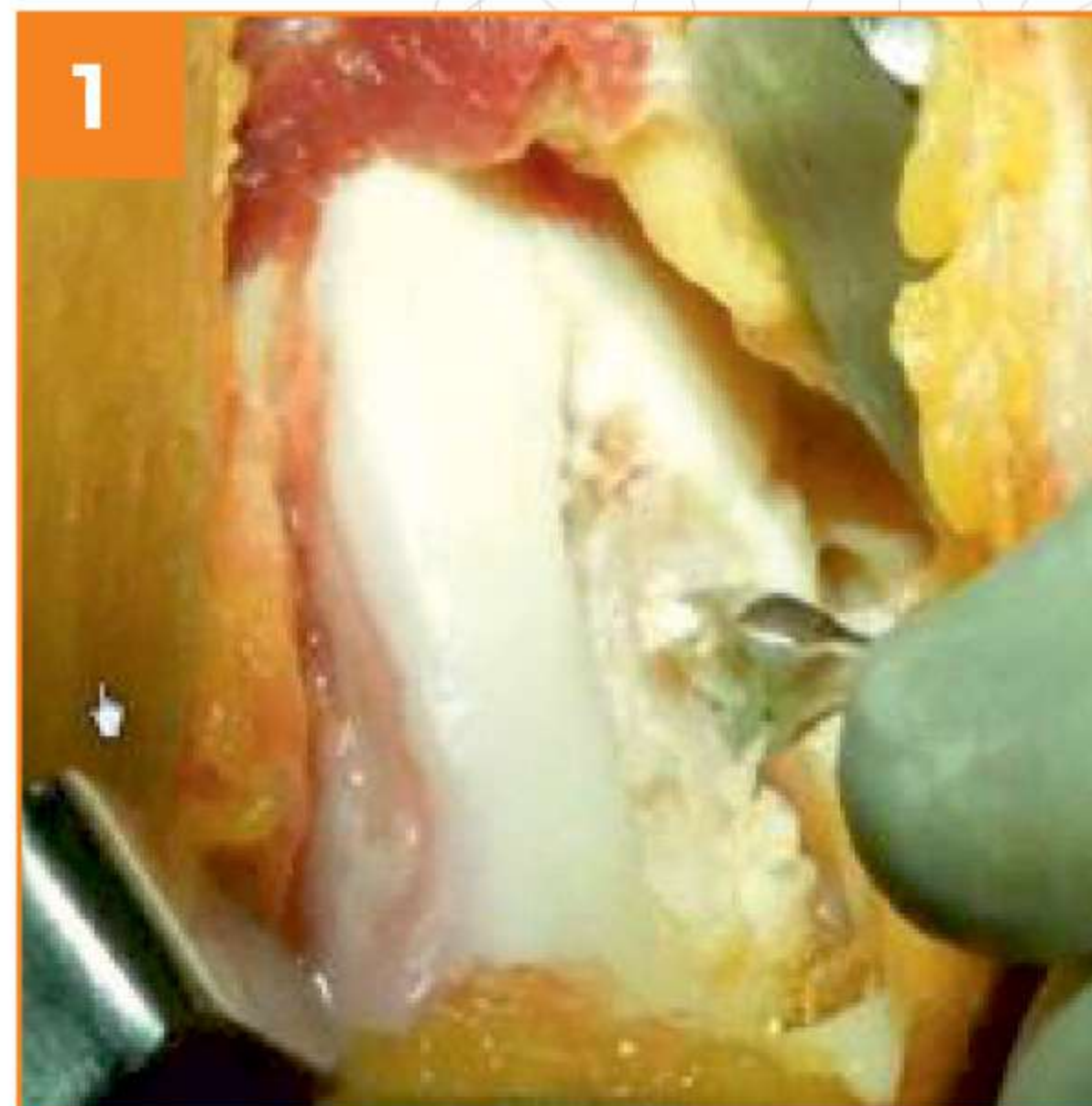
Do not use the vial if there is a visible colour change in the solution from pink/red to yellow/brown.

STEP 5

If the product is insufficient or not upto the quality standards enlisted on the COA, please initiate Recall procedure of the Delivery kit.

IMPLANTATION STEPS

- ▶ Approach and identify the defect area through mini-arthrotomy **(Fig. 1)** Measure defect with sterile scale. If defect is large ($>4 \text{ cm}^2$) use all 4 cell vials
- ▶ Using sharp curette, debride fibrous cartilage grown on the defect area, making it a contained area rim-creation **(Fig. 2 and 3)**
- ▶ Using drill bit, make 1mm shallow holes 2-3 mm apart (without penetrating sub chondral bone) for scaffolding purpose. **Ensure no bleeding (Fig. 3)**



IMPLANTATION STEPS

- ▶ Keep the prepared defect area parallel to floor / ceiling and gravity eliminating (**Fig. 4**)
- ▶ Inject final product onto the defect area. For complete coverage, start from the boundary and move towards the center. Wait for 7-8 minutes before closure (**Fig. 5**)
- ▶ Do not place any other material on the final product
- ▶ Carefully close the joint and immediately place a brace (**after dressing**)



POST IMPLANTATION PROCESS

AFTER SUCCESSFUL IMPLANT PROCEDURE

- ▶ Discard all used and unused materials including final product to Bio-waste as per hospital policy
- ▶ Return all instruments to the authorized party
- ▶ Complete the case file as per SOP
- ▶ Handover the COA to the clinician for their records

IN CASE OF ANY ADVERSE EVENTS/ SERIOUS ADVERSE EVENTS

- ▶ Report the details in the case file in the appropriate section
- ▶ Report to the Technical Director & Quality Assurance in-charge immediately on qa@regrow.in or **Call On 18002090309**
- ▶ Handover any material to the **REGROW®** Lab facility on immediate basics
- ▶ Follow the instructions of the clinician and hospital authorities

IN CASE OF CANCELLATION OF IMPLANTATION PROCEDURE

- ▶ Follow SOP for Recall of Final product as per **REGROW®** Lab Facility
- ▶ Follow Packaging Manual and SOPs
- ▶ Complete the case file

CARTIGROW[®]

CARTILAGE CELL THERAPY



FOR MORE DETAILS, PLEASE REACH OUT TO US:

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Technical Director

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CARTIGROW[®]



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