Meril

CARTIVELLE™

DELIVERY KIT MANUAL

For the Final Product
- AALCC (Autologous Adult Live Cultured Chondrocytes)

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DISCLAIMER & SCOPE

This manual describes the correct storage, receipt, handling and use of the **Cartivelle™** Delivery Kit. The Delivery Kit contains the final product **Cartivelle™** — Autologous Adult Live Cultured Chondrocytes (AALCC) — a living-cell product prepared for a specific, named patient and intended for surgical implantation to treat articular cartilage defects.

It is an operational reference for authorised personnel only — including operations and logistics staff; authorised distributors and logistics service providers; the treating physician; and hospital, surgical and operating-theatre (OT) staff. It is not a public document.

The Delivery Kit must be handled, stored, transported and used strictly as described in this manual and in accordance with the approved kit labelling and the Certificate of Analysis supplied with the product. This manual is supplementary to — and does not replace — the clinical judgement of the treating surgeon, the policies and procedures of the treating hospital, or the approved product information. In case of any doubt, contact Regrow Biosciences before implantation.

The product is supplied within the territory of India only and is regulated in accordance with the applicable requirements of the Central Drugs Standard Control Organisation (CDSCO) and the Drugs Controller General of India (DCGI).

IMPORTANT

If the kit is used, stored, transported or handled in any manner other than that specified in this manual, the quality, sterility, viability and integrity of the final cell-therapy product may be compromised — and it may become unsuitable for use.

CONTENTS

1. ABOUT THIS MANUAL

1.1 Purpose

This manual gives everyone who handles the **CARTIVELLE™** Delivery Kit a single, easy-to-follow reference — so that the final cell-therapy product reaches the patient sterile, viable, at the correct temperature, and within its shelf life.

1.2 Where the Delivery Kit fits - the treatment workflow

Treatment is a two-stage process. This manual covers the **CARTIVELLE™** Delivery Kit — the final product (stages highlighted below). The harvest of the patient's cartilage tissue is covered by the separate Cartivelle™ Transport Kit Manual.

1	2	3	4	5	6
Patient diagnosed with articular cartilage defect	**CARTIVELLE™** Transport Kit sent to hospital	Cartilage tissue harvested & blood sample collected	Kit returned to Regrow manufacturing facility	AALCC (**CARTIVELLE™**) cultured, tested & released	**CARTIVELLE™** Delivery Kit sent to hospital for implantation

1.3 Who uses this manual

Distributors & logistics service providers	Transport the kit at 2° C–8° C, keep the data logger ON, and deliver without delay.
Hospital & OT staff (scrub nurse, OT technician)	Receive, check and store the kit correctly; record temperature and times; support the implantation.
Treating physician	Verify the patient and the expiry date & time; implant the product within its shelf life.

2. CRITICAL PARAMETERS - TIME, TEMPERATURE & ASEPSIS

TIME	TEMPERATURE	ASEPSIS
• CARTIVELLE™ contains live cells with a limited shelf life. • Implant strictly before the expiry date and time on the label / COA. • Record the time of receipt and the time of implantation.	• Store and transport the kit at 2°C–8°C at all times. • Do not freeze. • Keep the data logger ON during transport. Record the temperature at receipt.	• The final product is for implantation into a patient. • Glass vials and canisters must not be opened outside the sterile field. • Maintain strict aseptic technique in theatre.

2.1 Temperature & Time at a glance

Storage & transport — all stages	2° C – 8° C at all times · Do not freeze
At the hospital, before implantation	2° C – 8° C until use
Data logger	ON throughout transport; temperature recorded at receipt
Shelf life	Use strictly before the expiry date & time on the label / COA

CRITICAL — AUTOLOGOUS PRODUCT

CARTIVELLE™ is an autologous product — it is manufactured from, and for, one specific patient. Before implantation, verify that the patient identity on the label matches the patient. The product must never be used for any other patient.

3. TEMPORARY STORAGE CONDITIONS

3.1 Do's and Don'ts (until use in OT/OR by Treating Physician)

✓ DO	× DO NOT
✓ Store in the OT store room or OT Pharmacy area as per hospital / doctor instructions. ✓ Keep the kit at 2° C–8° C at all times ✓ Keep the kit upright and dry. ✓ Check the expiry date & time on receipt. ✓ Keep the kit at 2° C–8° C until use.	× Do not open the Delivery kit or Accessory Kit other than inside the OT / OR. × Do not freeze the product. × Do not leave the kit out of temperature control. × Do not stack or place loads on the box. × Do not expose the kit to rain, sun or water. × Do not loose sight of the box until its utilization.

4. DELIVERY KIT - CONTENTS & IDENTIFICATION

4.1 Shipment Box

The Shipment Box is delivered to the hospital in a temperature-controlled shipment box. On receipt it should contain:

ITEM	QUANTITY
Corrugated outer carton	1 No.
Shipping box with lid	1 No.
Gel packs, 2° C–8° C	3 Nos.
Gel packs, –20° C	3 Nos.
Inner carton	1 No.
Data logger	1 No.
Docket Containing: Cartivelle™ Delivery kit Manual, COA , AE Reporting form, Mixing procedure chart, Insurance Label - 04	1 Set
CARTIVELLE™ Delivery Kit	1 No. (2 nos if Bilateral Case)
Accessory kit	1 No. (2 nos if Bilateral Case)

Handling Symbols

The Shipment Box carry the following symbols. Everyone who handles the box must recognize and respect them:

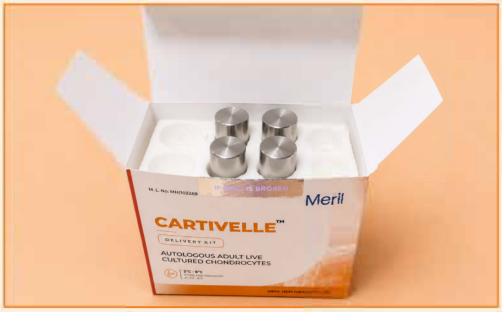
SYMBOL	WHAT IT MEANS
	General caution. Read and follow the instructions in this manual before handling the kit
	Keep dry. Protect the package from rain and moisture at all times.
	This way up. Keep the package upright. Do not tilt or invert.
	Fragile / keep dry. Handle with care to avoid damage; keep away from water.
	Do not stack. Do not place other boxes or any load on top of the package.

4.2 CARTIVELLE™ Delivery Kit

The Delivery Kit — Cartivelle™ (AALCC) — is supplied as living cells in sealed glass "V" vials. After manufacturing, these inner sealed glass vials are transferred into stainless-steel (SS) canisters inside a biosafety cabinet.

The Delivery Kit contains:

- The Delivery Kit contains the final product.
- Outer stainless-steel canisters - 4 Nos. - holding the sealed glass vials of final product.
- 8 vials if bilateral case.



CRITICAL - CHECK THE COA

The Certificate of Analysis supplied with the kit carries the product expiry date and time. Check it on receipt and confirm the product can be implanted within that limit.

5. INSTRUCTIONS ON USE OF CARTIVELLE™ (AALCC) FINAL PRODUCT

5.1 Final Product (Delivery Kit)

NAME	CONTENTS	FIGURE
FP Vial 1	Amber colored glass vial with silver gray aluminum cap containing Autologous Adult Live Cultured Chondrocyte Cells (Over 12 million cells in 0.4mL DMEM) in a SS canister	
FP Vial 2	Amber colored glass vial with silver gray aluminum cap containing Autologous Adult Live Cultured Chondrocyte Cells (Over 12 million cells in 0.4mL DMEM) in a SS canister	
FP Vial 3	Amber colored glass vial with silver gray aluminum cap containing Autologous Adult Live Cultured Chondrocyte Cells (Over 12 million cells in 0.4mL DMEM) in a SS canister	
FP Vial 4	Amber colored glass vial with silver gray aluminum cap containing Autologous Adult Live Cultured Chondrocyte Cells (Over 12 million cells in 0.4mL DMEM) in a SS canister	

NOTE:

- Total 04 FP Vials. Total of 4 vials consists of Over 48 million cells
- Autologous use only
- All four vials to be used
- All four FP Vials are packed inside a SS canister, present in the Delivery Kit
- All vials are non-sterile externally. The contents are sterile. Handle using aseptic technique.
- 4 vials if Unilateral Case/ 8 vials if bilateral case

DO NOT STOP INJECTING DURING THE IMPLANTATION. THE CELLS SHOULD BE INJECTED AT ONCE, HOWEVER, SLOWLY AND GENTLY COVERING THE ENTIRE DEFECT AREA (IN DRY ENVIORNMENT AND UNDER DIRECT VISION).

FIGURE 1. FINAL DEVICE ASSEMBLY

6. TREATMENT CANCELLATION AND RETURN OR RECALL

1. Do not tamper with or open the glass vials containing the final product (if they are not already opened). If opened, reinsert in the SS canister; place inside Delivery Kit carton.

2. If the Delivery kit has been opened, re-pack it as follows :
- **2.1** Repackage the kit exactly as it was received.
- **2.2** Keep gel packs in the correct positions
- **2.3** The Delivery Kit in upright position.
- **2.4** No material on top
- **2.5** No gel pack in direct contact with the Delivery kit.

3. Ensure the data logger is "ON".

4. Keep the Delivery Kit in the same Shipment Box.

5. Hand the Shipment Box to the authorised logistics agency and dispatch it to the Regrow facility on a First-In, First-Out (FIFO) priority basis

7. CONTACTS & SUPPORT

Regrow QA Staff	9028023346
Regrow Medical Support	9158986677
Regrow Operations: dispatch & logistics	9930470545
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