

CARTIVELLE™

TRANSPORT KIT

MANUAL

This manual describes the correct storage, handling, transport, packing and use of the **CARTIVELLE™** Transport Kit. The Transport Kit is used to collect cartilage tissue harvested from a patient who is diagnosed with articular cartilage defects, and the accompanying peripheral blood sample, and to transport them to the Regrow Biosciences Pvt. Ltd. manufacturing facility, where they are used to prepare the final product **CARTIVELLE™** [Autologous Adult Live Cultured Chondrocytes (AALCC)].

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Muktanand Marg, Chala,
Vapi - 396 191, Gujarat, India.
Website: www.merillife.com

DISCLAIMER & SCOPE

It is an operational reference for authorized personnel only - Meril and Regrow Biosciences sales, operations and logistics staff; authorized distributors and logistics service providers; and hospital, surgical and operating-theatre (OT) staff involved in the tissue harvest. It is not a public document.

The Transport Kit must be used strictly as described in this manual and in accordance with the approved kit labelling. 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 proceeding.

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 Organization (CDSCO) and the Drugs Controller General of India (DCGI).

This document contains confidential and proprietary information. The product **CARTIVELLE™** and all associated intellectual property are owned by Regrow Biosciences Pvt. Ltd. and are marketed, sold and distributed by Meril under an exclusive marketing, sales and distribution agreement. No part of this manual may be reproduced, copied, modified or disclosed beyond its intended users without the prior written consent of Regrow Biosciences Pvt. Ltd. and Meril.

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1. CRITICAL PARAMETERS - TIME, TEMPERATURE & ASEPSIS

Three things protect the harvested cartilage tissue from the moment it leaves the patient until it reaches the manufacturing facility. Every instruction in this manual exists to control one of them.

TIME	TEMPERATURE	ASEPSIS
• Cartilage tissue is a living material. • Harvest, label, re-pack and hand over to logistics without delay - ideally the same day. • Record the date and time at collection and at dispatch.	• Store the kit at 2°C-8°C at the Distributor/ hospital until use. • Transported at 15°C-28°C (empty kit and after Tissue harvest).	• The harvested tissue must stay sterile. • Maintain strict aseptic technique for the entire collection. • Open inner media tubes only at the point of use; close them immediately.

1.1 Temperature & time

Transport: facility → hospital (kit empty)	15°C – 28°C
Storage at the Distributor/hospital, before use	2°C – 8°C refrigerate; use earliest-expiry kit first
Transport: facility → hospital (after tissue harvest)	15°C – 28°C dispatch without delay

NOTE

Always use the kit with the earliest expiry date first. Never use a kit that is past its expiry date; discard expired kits as per the general disposal procedure.

2. DO'S & DON'TS - SUMMARY

This summary brings together the key rules from across the manual. It is not a substitute for reading the relevant section.

✓ DO	× DO NOT
✓ Keep the kit at the correct temperature at every stage (2°C–8°C in storage; 15°C–28°C in transit). ✓ Maintain strict aseptic technique during the harvest. ✓ Collect tissue directly into the inner media tubes; close them at once. ✓ Label every tube, container and the kit box completely. ✓ Re-seal the kit with the tamper-evident hologram. ✓ Dispatch the same day, without delay. ✓ Email operations@regrow.in after dispatch.	× Do not use an expired, damaged or tampered kit. × Do not leave the kit out of temperature control. × Do not open the inner media tubes except at the point of use. × Do not leave any tube, container or the kit box unlabeled. × Do not stack the boxes or expose them to rain, sun or water. × Do not delay dispatch after the harvest. × Do not use the kit in any way not described in this manual.

3. TRANSPORT KIT - CONTENTS & IDENTIFICATION

3.1 Collection kit box

The Transport Kit is delivered to the hospital inside a temperature-controlled Collection kit box. On receipt it should contain:

ITEM	QUANTITY
Corrugated outer carton of Collection kit	1 No.
Thermocol box with lid	1 No.
Gel packs, pre-cooled at 2°C – 8°C	2 Nos.
Certificate of Analysis (COA) of the kit	1 copy
Transport Kit Manual	1 copy
Patient Details and Case History Form	1 copy
Sterile Cartilage Tissue Harvester	1 No.
CARTIVELLE™ Transport Kit Contains: 2 Transport Kit vial containing Transport Nutrient Medium 1 EDTA Vacutainer Tube	1 No.

4. REQUEST OF TRANSPORT KIT STOCK & HOW TO MAINTAIN AT THE CENTRE



Corrugated shipment Box ready for dispatch, containing 2 Collection kit boxes.

Based on the requested quantity, the number of Transport Kits will be shipped to your designated location.



2 Collection kit box in 1 corrugated box



Collection kit box

- **Upon receiving the Collection kit Box:** Once the collection kit Box is received, carefully open it.
- **Wear Gloves:** Ensure that gloves are worn during the entire duration.



A4 Folder

- After opening the kit box, an A4 folder is found placed on top of the thermocol box. The folder contains the Patient Details and Case History Form, Transport Kit Manual, and Certificate of Analysis (COA).
- The thermocol box also contains the Cartilage tissue Harvester.
- Keep A4 folder and Cartilage tissue Harvester in the same box.

4. REQUEST OF TRANSPORT KIT STOCK & HOW TO MAINTAIN AT THE CENTRE

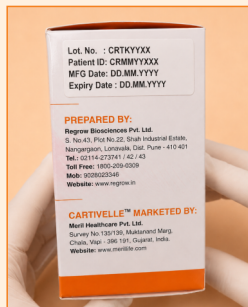


Placement of Transport Kit

Open the Thermocol box containing two gel packs and one transport kit. Remove the transport kit from the collection kit box and verify the details.



1



2



3



4

Handling the Transport kit(s) upon receipt

- **Check Kit Details:** Verify important details of the Transport Kit, including the Manufacturing Date and Expiry Date.
- Then quickly transfer the kit along with the gel packs to the refrigerator to maintain the 2°C-8°C temperature. Ensure refrigerator temperature is maintained between 2°C-8°C. Also, you can attach it to power supply backup to ensure continuity of the cooling.

5. UPON REQUEST FROM DOCTOR / HOSPITAL FOR TRANSPORT KIT



5.1 Collection kit box

Once the doctor confirms treatment initiation for a patient with an Articular Cartilage Defect, the assigned team member will retrieve the kit from the refrigerator along with the pre-cooled gel packs. The kit and gel packs will then be placed in the original Collection kit box received earlier and dispatched to the respective hospital or clinic for tissue collection.



5.2 A4 Folder

Once the kit box is opened, an A4 folder can be found placed on the thermocol box containing the Patient Details and Case History Form, along with the tissue harvester, manual, and COA.



5.3 Once the kit is received at hospital, the assigned member should take out the transport kit from the Collection kit box for Tissue collection.



5.4 Transport Kit Carton

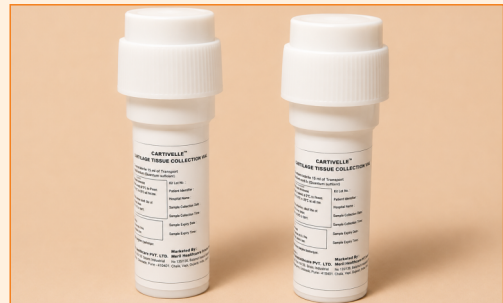
This is a **CARTIVELLE™** Transport kit used for collection of Cartilage Tissue Harvest from The Patient.



5.5 Transport kit contents

Transport Kit Contains:

2 Transport (Outer) containers consisting of 2 Universal (Inner) tubes carrying sterile transport medium for Collection of Cartilage Tissue Harvest and 1 EDTA tube for peripheral blood collection



5.6 Transport (Outer) Containers (2 Nos)

These containers are called Transport (Outer) containers.



5.7 Universal (Inner) Media Tubes

Universal (Inner) Tubes:

These universal tubes contain 15ml transport medium.



5.8 Once the cartilage tissue (min 5mm with 3-4mm of white cartilage tissue attached to 1-2mm of bone aseptically transfers using sterile forceps inside the universal tubes containing transport medium.

⚠ If bilateral case, take 2 cartilage tissue plugs and place inside another universal tube containing transport medium.



5.9 Labeling on Universal (Inner) Media Tubes

Maintain aseptic conditions during the entire time of sample collection.

After collecting the patient's cartilage tissue harvest, these vials are labelled with Patient ID, patient Name, Treating Physician Name, sample collection date, and Time.

In case a loose body (additional tissue) has been provided by the surgeon, then please collect it in the second transport container vial and label it as loose body.



5.10 Place Universal (Inner) Tube inside Transport (Outer) container

This Universal (Inner) Tube is then inserted into the Transport (outer) container.



5.11 Labeling Transport (Outer) Container

The Transport (outer) container is labeled with Patient ID, patient Name, Treating Physician Name, Hospital Name, Sample Collection Date and Time.



5.12 Purple Top vacutainer (EDTA) 1 no.

Peripheral Blood collection:

One EDTA tube is provided for collecting patient's peripheral blood. This blood will be used for the screening of Infectious Disease testing.



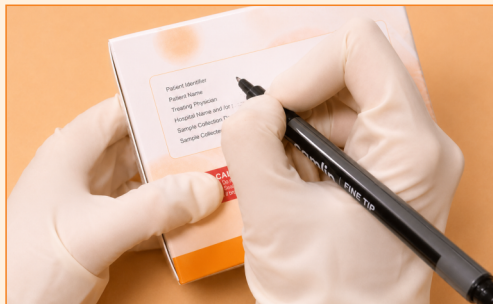
5.13 Contents placed back inside Transport Kit

All the contents are placed back into the Transport kit for final re-packaging.



5.14 Hologram Sticker pasted (Temper Evident)

Use the extra hologram sticker (temper Evident) provided inside the Transport kit at the time of re-packaging.



5.15 Labeling on Transport kit(backside)

Label the transport kit box with Patient Name and ID, Treating Physician Name and Hospital Name & city along with Sample Collection Date and Time



5.16 Placing Transport Kit before repacking Collection kit Box

The Transport Kit Box is kept in a pre-cooled temperature-controlled Box



5.17 Ready to dispatch Collection kit Box containing Transport Kit

Put the thermocol box inside the carton of Collection kit Box and securely cover it with a monsoon cover. Thereafter, hand it over to the authorized logistics agency for transportation to the Regrow facility, along with email confirmation to the Regrow Operations Team on operations@regrow.in

6. OVERVIEW OF TRANSPORT KIT DISTRIBUTION AND SAMPLE RETURN LOGISTICS

After receipt of Collection kit box at distributor site, remove the transport kit from the Collection kit box, check and take a note of its expiry date.



Keep transport kit along with gel packs for precooling at 2-8°C in refrigerator



Once the doctor calls for the case, put the transport kit along with 2 gel packs back in the same Collection kit box that was received earlier.



Take the Collection kit box to hospital for cartilage tissue collection



After receipt of Collection kit box at Hospital site, check the transport kit from the collection kit box for its integrity and expiry date



After sample collection, securely repack all components of the transport kit into the collection kit box and prepare it for shipment to the Regrow Laboratory.

7. CONTACTS & SUPPORT

7.1 Who to contact

Regrow QA Staff	9028023346
Regrow Medical Support	9158986677
Regrow Operations: dispatch & logistics	9930470545
Regrow lab Address	Regrow Biosceinces Pvt Ltd, Plot no. 22, Shah Industrial Estate, Nangargaon, Lonavala – 410 401
Email ID	ortho.patientsafety@regrow.in

8. REPORTING A PROBLEM

CRITICAL - REPORT BEFORE USE OR DISPATCH

Contact Regrow QA or Operations immediately — before using or dispatching the kit — if any of the following is found:

- A damaged or tampered transport kit box, or a broken tamper-evident hologram.
- An expired kit, or any kit past its expiry date;
- Any doubt about the identity or condition of the kit or its contents.