

OSSEOPRIMETM

TRANSPORT KIT

MANUAL

This manual covers the safe storage, handling, transport and use of the **OSSEOPRIMETM** Transport Kit - used to collect bone marrow from a patient diagnosed with Avascular Necrosis of hip Joint(s), together with a peripheral blood sample, and to transport them to the Regrow Biosciences Pvt. Ltd. manufacturing facility for the manufacture of **OSSEOPRIMETM** [Autologous Adult Live Cultured Osteoblasts (AALCO)].

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DISCLAIMER & SCOPE

It is an operational reference for authorised personnel only - Meril and Regrow Biosciences sales, operations and logistics staff; authorised distributors and logistics service providers; and hospital, surgical and operating-theatre (OT) staff involved in the bone marrow harvest. This 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 Pvt. Ltd. before proceeding.

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

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1. CRITICAL PARAMETERS - TIME, TEMPERATURE & ASEPSIS

Three things protect the Bone marrow Harvest from the moment of its collection until it reaches the manufacturing facility. Every instruction in this manual exists to control one of them.

TIME	TEMPERATURE	ASEPSIS
• Bone marrow is 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 15°C -28°C at the hospital until use. • Transport at 15°C –28°C (kit empty, and after harvest).	• The harvested bone marrow must stay sterile. • Maintain strict aseptic technique for the entire collection. • Open inner Sodium Heparin tubes only at the point of use; pack them immediately.

1.1 Temperature & time

Transport: facility → hospital (kit empty)	15°C – 28°C
Storage at the Distributor/hospital, before use	15°C – 28°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 all times (15°C –28 °C in storage and transit). ✓ Maintain strict aseptic technique during the bone marrow harvest. ✓ Transfer the harvested bone marrow directly into the inner sodium heparin tubes using a sterile syringe and needle. ✓ Place the filled heparin tubes into the transport container and securely tighten the screw cap. ✓ 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 unlabelled. × 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 in a 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
Luer Lock syringe (20 ml capacity)	2 No.
Bone Marrow Harvest Needle	1 No.
OSSEOPRIME™ Transport Kit Contains: 3 Transport Kit vial containing Sodium Heparin Vacutainer Tubes (One additional heparin tube is given as spare) 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 Bone Marrow collection kit boxes.



2 Bone Marrow collection kit boxes in 1 corrugated shipment box

Based on the requested quantity, the number of Bone Marrow collection kit boxes will be shipped to the designated location.



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 of 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 Bone Marrow Harvest Needle.
- Keep A4 folder and Bone Marrow Harvest Needle in the same box.



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 and then place the kit back in the same box.



Inside there is 2 Luer Lock syringes (20 ml capacity) used for bone marrow transfer to Sodium Heparin tube. Keep these syringes inside the thermocol box.



Placement of Transport Kit

Remove the gel packs and store them in a refrigerator (not the freezer) for use in maintaining the collection kit box temperature during bone marrow sample transportation.

All remaining kit components, including the Transport Kit, Bone Marrow Harvest Needle, and A4 folder, should be stored in the collection kit box at ambient temperature until use.

5. UPON REQUEST FROM DOCTOR / HOSPITAL FOR TRANSPORT KIT



5.1 Collection kit box

Once the doctor confirms treatment initiation for a patient with AVN of the hip joint(s), retrieve the pre-cooled gel packs from the refrigerator and place them back into the original Collection kit box received earlier.

The folder included in the kit contains the Patient Details and Case History Form, User Manual, and Certificate of Analysis (COA). The thermocol box also contains the Bone Marrow Harvest Needle.

The complete collection kit should then be dispatched to the respective hospital or clinic for bone marrow collection.



5.2 A4 Folder

Upon receipt and opening of 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, User Manual, and Certificate of Analysis (COA). The thermocol box also contains the Bone Marrow Harvest Needle.



5.3 Placement of Transport kit

Once the Collection kit is received at the hospital, the paramedic staff should take out the transport kit along with sterile and ready-to-use bone marrow harvester needle, along with 2 Luer Lock syringes (20 ml capacity).



5.4 Transport Kit Carton

This is an OSSEOPRIME™ Transport kit used for the collection of Bone Marrow from the Patient.



5.5 Transport kit contents

Transport Kit Contains:

Three transport (outer) containers comprising three sodium heparin tubes for patient bone marrow collection, one additional sodium heparin tube as a spare, one EDTA tube for peripheral blood collection, and one vial of heparin solution.



5.6 Transport (Outer) Containers (3 Nos)

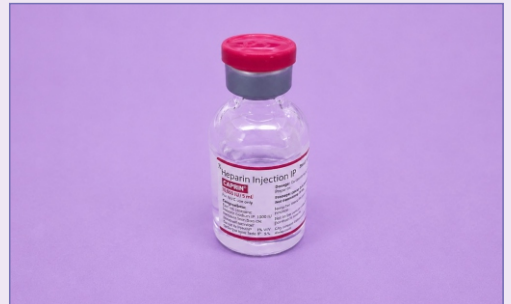
These containers are called Transport containers (Outer).



5.7 Sodium Heparin Tubes:

Sodium Heparin Tubes:

These sodium heparin tubes are used for the collection of the patient's bone marrow.



5.8 Heparin Vial:

The heparin solution vial to be used for the flushing of syringes and bone marrow needles to avoid bone marrow clotting.



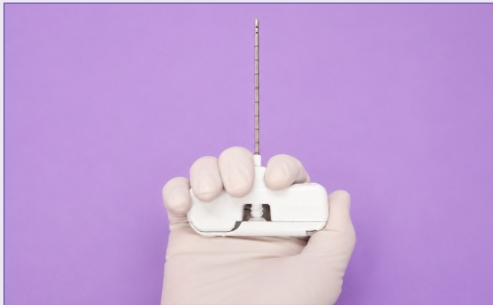
5.9 Flushing of Syringe

Aspirate the heparin solution from the vial and flush the syringe.



5.10

Perform flushing of the bone marrow harvest needle using the syringe containing heparin solution.



5.11

The bone marrow harvest needle is now ready for bone marrow harvest and collection.



5.12

After collection of the bone marrow harvest from the patient, transfer minimum 4ml to maximum 5 ml of bone marrow directly into each inner sodium heparin tubes using a sterile syringe.

Gently mix the tube after bone marrow transfer into the vial.



5.13 Labelling on Sodium Heparin Tubes

- Maintain aseptic conditions during the entire time of the collection of the patient's Bone Marrow harvest.
- After collection of bone Marrow, these Prelabelled tube (with Patient ID) are to be labelled with Patient Name.
- For bilateral case, collect the bone marrow harvest in all three sodium heparin tubes provided.
- (4-5 mL of bone marrow each, total 12-15 mL in 3 vials)
- For unilateral case, collect the bone marrow harvest in two sodium heparin tubes.
- (4-5 mL each, total 8-10 mL in 2 vials)
- Extra 1 Sodium Heparin Tube is provided in the kit in case any breakage or damage is observed in existing tubes, this can be used.



5.14 Place Sodium Heparin Tube inside Transport (Outer) container

After bone Marrow collection, place the filled sodium heparin tubes in the outer screw-cap container and ensure they are properly packed and securely sealed.



5.15 Labelling Transport (Outer) Container

The Transport (outer) container to be labelled with Patient ID, Patient Name, Treating Physician Name, Hospital Name, Sample Collection Date, and Time.



5.16 Purple Top vacutainer (EDTA) 1 no.

Peripheral Blood collection:

One EDTA tube is provided for collecting the patient's peripheral blood (3-4 mL). This blood will be used for the screening of Infectious Disease testing.



5.17 Contents placed back inside Transport Kit

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



5.18 Hologram Sticker pasted (Temper Evident)

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



5.19 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.



5.20 Placing the Transport Kit and repackaging of the collection kit Box

The Transport Kit Box is to be kept in a temperature-controlled Box along with precooled gel packs.



5.21 Ready to dispatch the collection kit Box containing the Transport Kit

Put the thermocol box inside the carton of the 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, check the transport kit from the collection kit box for its integrity and expiry date.



Keep transport kit in the same Collection kit box and keep the gel packs in refrigerator



Once the treating physician calls for the case, put the 2 pre-cooled gel packs back in the same collection kit box that was received earlier.



Take the Collection kit box to hospital for Bone Marrow 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 Biosciences 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 Collection 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.