Meril

OSSEOPRIME™

DELIVERY KIT MANUAL

For the Final Product
- Autologous Adult Live Cultured Osteoblasts (AALCO)

Manufactured By:
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DISCLAIMER & SCOPE

This manual describes the correct storage, receipt, handling and use of the **OSSEOPRIME™** Delivery Kit. The Delivery Kit contains the final product **OSSEOPRIME™** — Autologous Adult Live Cultured Osteoblasts (AALCO) — a living-cell product prepared for a specific, named patient and intended for surgical implantation to treat Avascular Necrosis of hip Joint(s).

It is an operational reference for authorized personnel only — including operations and logistics staff; authorized 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 Organization (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 **OSSEOPRIME™** 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 **OSSEOPRIME™** Delivery Kit — the final product (stages highlighted below). The separate **OSSEOPRIME™** Transport Kit Manual covers the harvest of the patient's Bone marrow.

1	2	3	4	5	6
Patient diagnosed with Avascular Necrosis of hip Joint(s)	**OSSEOPRIME™** Transport Kit sent to hospital	Bone marrow Harvested & blood sample collected	Kit returned to Regrow manufacturing facility	AALCO (**OSSEOPRIME™**) cultured, tested & released	**OSSEOPRIME™** Delivery Kit sent to hospital for implantation

1.3 Who uses this manual

Distributors & logistics service providers	Transport the kit at 15°C -28°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
• **OSSEOPRIME™** contains live cells with a limited shelf life. • The product must be implanted before the expiration date and time stated on the label and Certificate of Analysis (COA). • Record the time of receipt and the time of implantation.	• Store and transport the kit at 15°C -28°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	15 °C – 28 °C at all times · Do not freeze
At the hospital, before implantation	15 °C – 28 °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

OSSEOPRIME™ 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 15°C -28°C at all times ✓ Keep the kit upright and dry. ✓ Check the expiry date & time on receipt. ✓ Keep the kit at 15°C -28°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 lose sight of the box until its utilization.

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. 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 following items:

IMPLANT KIT BOX

A4 DOCKET

IP NEEDLES
2 NOS. (3 NOS. IF BILATERAL CASE)


INSIDE OF THERMOCOL BOX

TEMERAPTURE DATE LOGGER

DELIVERY KIT

ITEM	QUANTITY
Corrugated outer carton	1 No.
Shipping thermocol box with lid	1 No.
Docket Containing: OSSEOPRIME™ Delivery kit Manual, COA , AE Reporting form, Mixing procedure chart, Insurance Label-04 Nos.	1 Set
IP needle	2 nos. (3 nos. if Bilateral Case)
Gel packs, 15°C–28°C	2 Nos.
Data logger	1 No.
OSSEOPRIME™ Delivery Kit	1 No.
Accessory kit	1 No. (2 nos if Bilateral Case)

4.2 OSSEOPRIME™ Delivery Kit

The Delivery Kit — **OSSEOPRIME™** (AALCO) — is supplied as living cells in sealed glass "V" vials. After manufacturing and packaging, these inner sealed glass vials are transferred into stainless-steel (SS) canisters.

The Delivery Kit contains:

- The Delivery Kit contains the final product.
- Outer stainless-steel canisters 1 No. holding the sealed glass vial of final product.
- 2 vials if bilateral case.

DELIVERY KIT CARTON

INSIDE OF DELIVERY KIT CARTON


OUTER STAINLESS-STEEL CANISTERS


SEALED GLASS VIALS OF FINAL PRODUCT

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 OSSEOPRIME™ (AALCO) FINAL PRODUCT

5.1 Final Product (Delivery Kit)

NAME	CONTENTS	FIGURE
FP Vial 1	Each single use glass vial (Total volume of suspension 1.6mL) contains: Autologous Adult Live Cultured Osteoblasts (over 48 million cells) in DMEM (Dulbecco's Modified Eagles Medium) + 20% HSA (1:1)... q.s.	

NOTE:

- Amber colored glass vial sealed with silver gray aluminum cap placed in the SS canister.
- One Vial consists of Over 48 million cells
- Autologous use only
- The whole content of vials to be used
- One Vial is packed inside a SS canister, present in the Delivery Kit
- The vial is aseptically packed. The contents are sterile. Handle using aseptic technique.
- One vial per hip joint (Two vial for Both Hip Joints)

6. TREATMENT CANCELLATION AND RETURN OR RECALL

Follow these steps if the treatment is cancelled (returned), or if the product has to be recalled to the Regrow facility.

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 authorized 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
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Regrow Operations: dispatch & logistics	9930470545
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