

SOP-00633: Commercial Treatment Site Final Product Handling – Key Updates (v10 → v11)

Purpose:

This summary highlights the major changes introduced in Version 11 compared to Version 10 and explains why these updates matter for Kite Authorized Treatment Centers (ATCs).

Summary of Changes

Section	Version 10	Version 11	Why It Changed
References	Cited STD-00195 (Global Requirements)	Removed reference to STD-00195	Focus on U.S.-specific requirements
Definitions	Included Kite Konnect® portal and Oracle EBS	Removed Kite Konnect® and Oracle EBS; added Package Insert (USPI) and MRN example	Clarified scope and added relevant terminology
Responsibilities	QA – Site Qualification	Regional Quality Operations (RQO)	Reflects current organizational structure and department name update
Equipment	LN ₂ shipper, vapor phase freezer	Added additional storage option: mechanical freezer (-80°C ± 10°C)	Provides alternative storage options (see Attachment 2). Prior approval from Kite Quality Manager required for implementation at site.
Attachments	Attachment 2: List of Approved Kite Products	Replaced with: Attachment 2: Alternative Storage	Supports new storage flexibility at -80°C
Temperature Verification	Manual entry via URLs; troubleshooting steps included	QR code scanning; removed troubleshooting section (replaced with: call Kite Konnect® for assistance)	Streamlined process and reduced complexity
Shipment Contents	Not specified	Listed contents: Package Insert, Dosage Info Report, return paperwork	Improves transparency and readiness
Infusion Instructions	Included thawing and infusion steps	Removed steps regarding infusion (refer to USPI)-Thawing instructions still included.	Infusion is a medical task; SOP scope is limited to receipt, storage and handling of final product
Visuals	Older photos of LN ₂ shipper and foam rack	Updated photos for LN ₂ shipper labels, zip tie verification, foam cassette rack	Improves clarity and usability

Major Additions in Version 11- More Details

- **Alternative Storage Option Introduced**
 - **Note: To use this storage option, you must contact your Kite Quality manager for further instructions prior to implementation.**
 - Added **mechanical freezer (-80°C ±10°C)** as an approved short-term storage option for up to **90 days**.
 - Detailed instructions provided in **Attachment 2: Alternative Storage**, including:
 - Conditions for transfer to thaw location.
 - Restrictions (cannot return to ≤ -150°C after -80°C storage).
 - Monitoring and documentation requirement
 - Added dry ice as an option for short-term transfer during thaw preparation.

Structural & Content Changes

- **Removed References**
 - Deleted reference to **STD-00195 (Global Requirements)**.
 - Removed definitions related to **Kite Konnect® portal** and **Oracle EBS** (out of scope for treatment site staff- staff that perform packing/shipping of the apheresis material will refer to SOP-00309).
- **Updated Definitions**
 - **Hospital Patient ID** now includes example: *Medical Record Number (MRN)*.
 - Added definition for **Package Insert (USPI)**.
- **Department Name Change**
 - "Quality Assurance – Site Qualification" updated to **Regional Quality Operations (RQO)** to reflect updated department name. This is your Kite Quality contact.

Process & Instruction Updates

- **Temperature Verification**
 - Introduced **QR code scanning** for Cryoport® and Marken LN2 shippers to verify temperature data and alarm status.
 - Removed troubleshooting section (previously Section 8.9); now instructs sites to **call Kite Konnect® for guidance**.
- **Shipment Contents**
 - SOP now specifies items included in LN2 shipper:
 - Package Insert
 - Dosage Information Report
 - Return paperwork for empty dewar
- **Visual Updates**
 - Updated pictures for:
 - Serialized zip tie and waybill reference.
 - Foam cassette rack (new design).
 - LN2 shipper exterior labels for Cryoport® and Marken.

- **Infusion Instructions**

- Removed infusion steps from SOP (out of scope for this SOP; Treatment Site staff should refer to USPI for instructions on infusion).

Attachments

- **Removed:** Attachment 2 from v10 (List of Approved Kite Products).
- **Added:** Attachment 2 in v11 (Alternative Storage at $-80^{\circ}\text{C} \pm 10^{\circ}\text{C}$).