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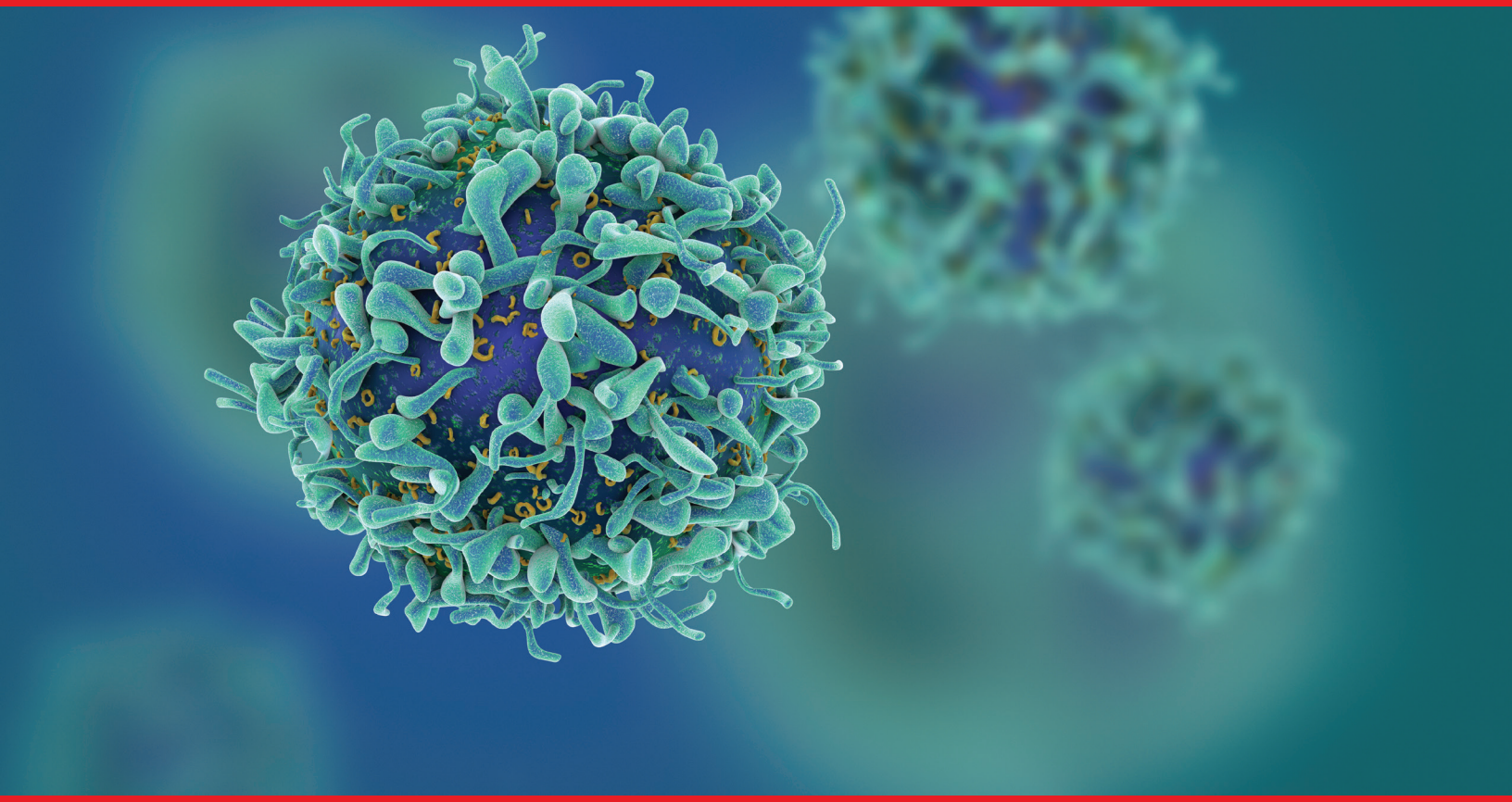


Receipt and Storage Manual

Version 5
March 2025

Requirements for US Commercial CARVYKTI®

1 Receipt and Storage Manual

This manual provides requirements to support supply chain standards within the CARVYKTI® commercial manufacturing process related to receipt and storage of the manufactured product.*

The requirements in this manual are intended to be incorporated into each treatment center's operating procedures.

Contents

***Please note that the term receipt as used in this manual is specific to the requirements set forth in this manual and shall NOT apply to any reference or use of the term receipt in any document or agreement outside of this manual that is related to CARVYKTI®.**

Abbreviations

AWB	Air Waybill
CoC	Chain of Custody
CoI	Chain of Identity
DIN/SEC-DIS	Donation Identification Number/Single European Code/Apheresis ID
LN2	Liquid Nitrogen
WBC	White Blood Cell
PPE	Personal Protective Equipment
PQC	Product Quality Complaint
TOR	Temperature Out-of-Range

Definition of Terms

CoC/CoI Portal	The Chain of Custody (CoC)/Chain of Identity (CoI) management portal is used to track the handoffs throughout the CARVYKTI® order fulfillment process.

Receipt and Handling of CARVYKTI®

Shipment Types

There are two types of shipments related to the receipt and handling of CARVYKTI®:

1. CARVYKTI® from the manufacturing facility to the treatment center.
2. Empty DV10 Liquid Nitrogen Shipper back to Janssen's courier for recharge or reuse.

If a situation falls outside of these scenarios, contact your designated Janssen representative for further instructions.

Shipment of CARVYKTI® From the Manufacturing Facility to the Treatment Center

1. **Shipment initiation:** Janssen will initiate pickup of the product by its designated authorized courier once it is released from manufacturing quality and a delivery date is selected.
2. **Shipment confirmation:** The courier will then issue an automated shipment confirmation to the treatment center via email.
   - The confirmation will reference the patient number for shipment tracking.
   - The confirmation will also reference the AWB for the shipment.
   - A print-out of the same AWB is provided in the shipper kit pouch inside the DV10 Liquid Nitrogen Shipper.
3. **Shipment notification:** Before delivery, the courier will send one notification to the treatment center.
   - On the day of delivery, this notification will be received when the shipment is within a 5-mile (8-kilometer) radius of the treatment center.
   - If there are any delays in shipment, the courier will email or directly call the designated treatment center contact.
4. **Receipt of DV10 Liquid Nitrogen Shipper:** The product will arrive at the treatment center inside the DV10 Liquid Nitrogen Shipper between 9 to 11 a.m. local time, or as designated by the treatment center.
5. **Pickup of empty DV10 Liquid Nitrogen Shipper:** Janssen will coordinate with the courier to pickup the DV10 Liquid Nitrogen Shipper from the treatment center for return to Janssen the afternoon of receipt at 2 p.m. local time, or as designated by the treatment center.

If the empty DV10 Liquid Nitrogen Shipper will not be ready for pickup at 2 p.m. local time or the agreed upon time, contact your designated Janssen representative.

Unpacking the Shipment

Before unpacking the DV10 Liquid Nitrogen Shipper, make sure the following items are readily available as they are not provided by Janssen:

- Cryogloves
- Safety glasses
- Wire cutter

Follow treatment center requirements for PPE when handling any cryopreserved product and equipment.

Confirm the following materials are included inside the outer shipper case:

- Labeled consignee kit pouch, which will be needed when the empty shipper is picked up for return to the courier. The consignee kit pouch is inside the outer shipper case and includes:
  - 1 zip tie for use on the outer shipper case
  - AWB for return of empty DV10 Liquid Nitrogen Shipper

Important—Contact your designated Janssen representative if:

- The DV10 Liquid Nitrogen Shipper case is not secured or not intact.
- The zip tie is missing from the outer case.
- The patient identifier listed on the AWB does not match the intended patient.
- The DV10 Liquid Nitrogen Shipper's EVO-IS ID (last 4 digits listed on the AWB) does not match the DV10 Liquid Nitrogen Shipper or if the Seal # on the red tamper evident seal does not match the Seal # listed on the AWB.
- Any contents are missing from the consignee kit pouch.

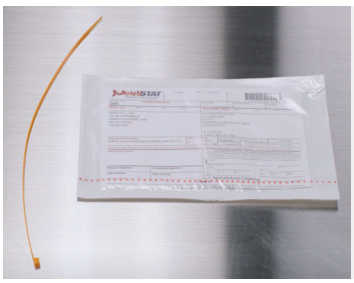
Receiving the DV10 Liquid Nitrogen Shipper

- Take the AWB and the packing insert from inside the clear packing envelope on outer case of the DV10 Liquid Nitrogen Shipper case.

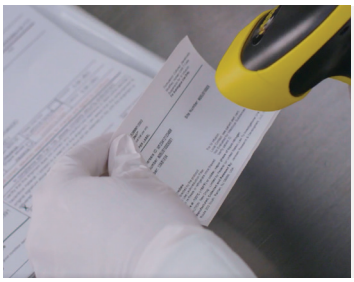
Using your own wire cutters, cut and discard the zip tie securing the zippers. These wire cutters are not included in the shipment.

Unzip and lift open the shipper case lid.

Inside the outer shipper case is a pouch. Verify that it contains the consignee kit pouch.

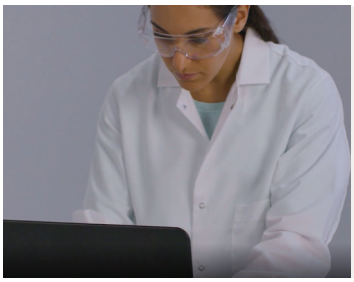


The consignee kit pouch includes materials for returning the shipper: one zip tie for the outer shipper case and the air waybill to return the empty shipper.



Take the packing insert and confirm with the CoI record in the CoC/CoI Portal. Scan or enter the packing insert to confirm the product is correctly associated with the CoI record in the CoC/CoI Portal.

⚠ You will also be prompted to answer additional questions regarding checks of shipment integrity. Include comments as necessary.



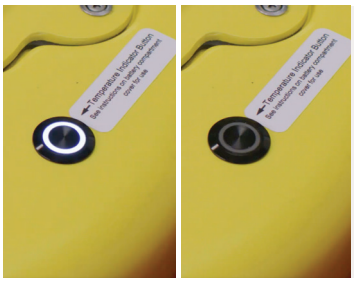
In the CoC/CoI Portal, confirm the EVO-IS ID number (last 4 digits on the AWB) matches the EVO-IS ID number on the DV10 Liquid Nitrogen Shipper lid.

Confirm the Tamper Seal number on the DV10 Liquid Nitrogen Shipper lid matches the number on the AWB.

Press and release the light indicator on the DV10 Liquid Nitrogen Shipper lid and wait five seconds or scan the QR code on the DV10 Liquid Nitrogen Shipper lid.

Scanning the QR code will direct you to a web page that displays the last reported payload temperature with the last recorded temperature reading.

A steady white light or green check mark received from the web page of the QR code, indicates the temperature is within range and you can continue.



If the light indicator shows a flashing white light, or a red check mark from the web page of the QR code, a Temperature Out-of-Range, or TOR, has occurred. Indicate this when responding to CoC or CoI receipt questions in the CoC/CoI Portal.

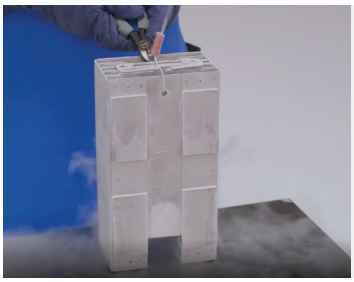
If Temperature Out-of-Range is noted, complete the TOR form located in Janssen's File Sharing Tool (MBOX) after the product is removed from the shipper and email it to DL-JanssenCAR-T_Vein-to-Vein_US@its.jnj.com.

If there was no temperature excursion, continue preparing to remove the product from the shipper.

Unpacking CARVYKTI®

It is recommended to have two personnel work together during the unpacking process. Make sure all necessary PPE is on or in place before unpacking and that you are following your local PPE processes and procedures before unpacking. Additionally, the product must be placed in an LN2 Freezer immediately following unpacking from the shipper and verification of CoC/CoI.

Make sure all necessary PPE is on or in place before unpacking. Also make sure the Drug Product Receipt Checklist for Treatment Center form is available for reference and completion.



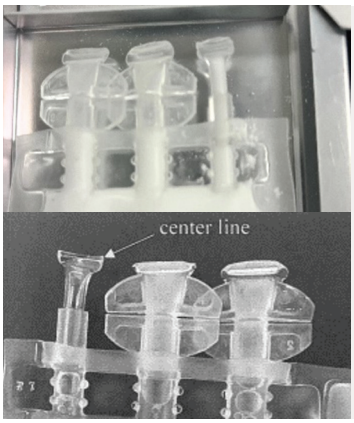
Using wire cutters, not included in the shipment, cut the tamper evident seal on the lid. Remove the lid and lift the cassette rack out.

Confirm product cassette was not exposed to ambient temperature greater than 3 minutes. It is critical to pack the cassette into the LN2 freezer quickly to avoid thawing of the product.

Cut and discard the tamper evident seal on the cassette rack and remove the cryogenic containment pouch containing CARVYKTI® from the rack slots.

Cut open the pouch and remove the cassette.

Before placing the cassette into local LN2 Freezer, confirm the patient number matches on the cassette label, the AWB, and in the Coc/Col Portal.



When the cassette containing the product bag is removed from the LN2 Freezer, and is in the frozen state, the product bag is brittle.

Open the cassette and ensure the CARVYKTI® product is positioned with the ports at the top.

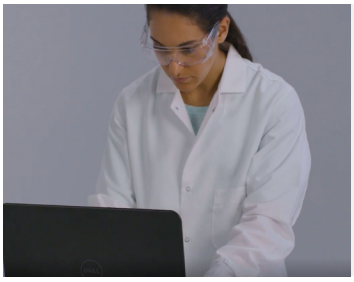
There are three (3) ports on the bag as shown to the left; which must be intact upon receipt.

It is very important to handle the cassette and product with care to avoid damage.

If there are any issues with cassette or the product, please contact your designated Janssen representative immediately and report a PQC.

Place the cassette with CARVYKTI® into the LN2 Freezer and do not separate the cassette from the product until preparing for infusion.

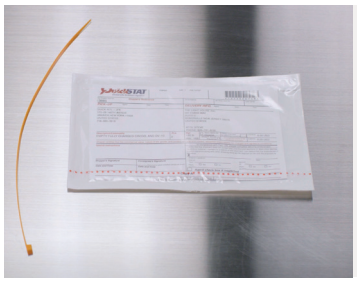
Remove the shipper lid and then place the empty cassette rack back into the shipper. Finally, close the lid.



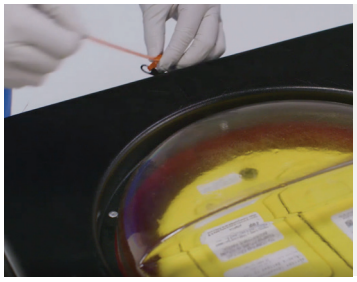
Complete the Shipment and Product Receipt Checklists under the Finished Product Delivery step within the CoC/CoI Portal.

Returning the DV10 Liquid Nitrogen Shipper

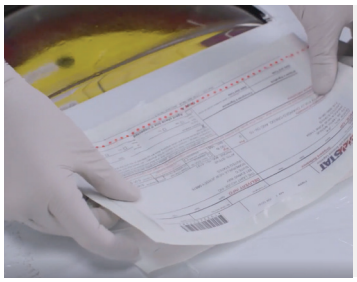
After completion of the entire Finished Product Receipt process, prepare the empty DV10 Liquid Nitrogen Shipper for shipment:



Gather the unused zip tie and the new AWB from the consignee kit pouch for the DV10 Liquid Nitrogen Shipper.



Secure the inner shipper case with the zip tie and then secure the outer shipper case with buckles.



Place the AWB into the clear packing envelope for courier pickup. The DV10 Liquid Nitrogen Shipper is now ready for pickup.

Janssen will coordinate with the courier to pick up the empty DV10 Liquid Nitrogen Shipper from the treatment center at the agreed upon pickup time. Contact your designated Janssen representative immediately if there are any constraints for getting this shipment ready for the agreed upon pickup time.

Storage of CARVYKTI®

Storing CARVYKTI®

The product must be stored according to the conditions on the label, in a secure location with limited access. During storage, the product must not be separated from the cassette. The packaging is designed to protect the product from breakage and damage and should not be separated.

CARVYKTI® must be kept frozen at less than or equal to -120°C, vapor phase of LN2.

What are storage temperature monitoring requirements?

1. Temperature conditions during on-site storage of CARVYKTI® must be monitored and recorded (e.g., temperature logs or data, charts or graphs from temperature monitoring equipment or devices).
2. The use of a temperature monitoring device is required for the storage of all products. All documentation and data of the storage temperature must be retained in accordance with your local records retention policy, and applicable legal and regulatory requirements.
3. Temperature monitoring equipment must be calibrated in accordance with the manufacturer's recommendations.
   - When the temperature monitoring device is equipped with audible and visible alarms to attract immediate attention in the event of a TOR occurrence, the proper functioning of these alarms must also be periodically tested and documented.
4. The output of the temperature monitoring device must be verified and recorded on a temperature log or temperature alarm log daily, during treatment center working days.
   - It is not necessary to check the temperature monitoring equipment on weekends and holidays. If a TOR event occurs during the weekend or holiday, Janssen should be notified immediately.
5. Temperature logs must identify or link to the temperature monitoring device and, if applicable, the LN2 Freezer.
   - Links can be through the serial number or other unique identifier.
6. CARVYKTI® must be kept frozen at less than or equal to -120°C, vapor phase of LN2 Temperature monitoring device with audible and/or visible alarms:
   - The audible and/or visible alarm will alert the cell processing laboratory staff of a TOR situation and the procedure for reporting a TOR must be followed.
   - Even when the system has not alarmed, the temperature records generated by the system should be periodically reviewed to verify all temperature measurements were within range.

Temperature Out-Of-Range (TOR) Events

What To Do

Immediately upon discovery of a TOR reading(s), via the flashing white light on the DV10 Liquid Nitrogen Shipper lid, or Red check mark from the QR code, take the following steps:

Quarantine the affected product and affiliated supplies. It is important not to use supplies that have experienced a temperature excursion (See *Quarantining* sub-section).

1. Remove the product from the DV10 Liquid Nitrogen Shipper and place the product in the LN2 Freezer following the instructions provided on page 10 of this manual under, “Storage of CARVYKTI.”
2. Immediately contact your designated Janssen representative of the TOR occurrence and discuss the potential impact. Provide them with the last 4 digits of the EVO-IS # and patient number.
3. Complete the Temperature Out-Of-Range (TOR) Report Form immediately. Instructions are provided on the form for completion and submission to Janssen.
4. Janssen will complete the bottom of the TOR Report Form and indicate whether the product is acceptable for use or not.

   For a DV10 Liquid Nitrogen Shipper TOR event, there is no need to attach the temperature reports to the TOR Report Form. The Janssen Vein-to-Vein Team will extract the data from the EVO-IS shipper readout.
5. For Storage TORs, which may occur while the product is in storage on-site, contact Janssen at 1-800-526-7736 if in the United States. For all other regions, please contact your local Janssen representative.

Quarantining

If a concern is found by the treatment center upon receipt and it is necessary to quarantine the product (e.g., damaged, TOR, product quality complaint), please follow the steps below:

1. Immediately contact your designated Janssen representative.
2. Physically separate the product being quarantined. Follow local quarantine procedures for maintaining product segregation.
3. While in quarantine, the product must be stored and handled according to the manufacturing requirements (e.g., LN2 freezer) and procedures.

   This will prevent further deterioration or damage to the product while the viability of the product is being assessed.
4. Once quarantined, the product must remain separated until further notification is received from Janssen.
5. **If the product was quarantined due to a TOR,** the completed TOR Form will indicate if the product is acceptable for use or not.
6. **If the product has been quarantined due to product quality complaint,** provide the details and a photograph of the product and/or packaging to the appropriate Janssen representative.
7. After an assessment, Janssen will review outcome and next steps.

   If indicated that the product is acceptable for use, follow your local procedures to moving product into available inventory.

   If indicated that the product is not acceptable:

   - Identify the product as 'ready to destroy'.
   - Contact your Janssen representative to discuss the Credit and Replacement Policy.

Damaged or Lost Product

If the product is damaged while stored at the treatment center, follow the instructions for Quarantining. Contact your designated Janssen representative to review instructions for next steps.

Loss of product is considered a critical situation by regulatory authorities. If the product is lost while stored at the treatment center, as soon as loss is confirmed, immediately:

- Contact your designated Janssen representative within 24 hours.
- Conduct an investigation as per your local procedures.
- In the United States, Contact Janssen at 1-800-526-7736. All other regions, please contact your local Janssen representative.

Product Quality Complaint Reporting of CARVYKTI®

Reporting a Product Quality Complaint

If there is damage to the product or cassette at Receipt and Storage or at Thaw and Infusion of Final Product, call 1-800-526-7736 to report the complaint and also inform your Janssen representative within 24 hours.

In both instances, you will need to provide the following information:

- Order Number
- Lot/Batch Number
- Expiry Date
- Patient's Initials
- DIN
- MRN
- Short Description of the PQC Event

Receipt and Storage Manual

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For questions related to the information in this manual,
contact your designated Janssen representative.

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