



Division of Cellular Therapy

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Gamida Cell: Transplant Center Receive and Store

DOCUMENT NOTES:**Document Information****Revision:** 02**Vault:** ABMT-General-rel**Status:** Release**Document Type:** ABMT**Date Information****Creation Date:** 16 Jan 2024**Release Date:** 30 Jan 2024**Effective Date:** 30 Jan 2024**Expiration Date:****Control Information****Author:** JLF29**Owner:** JLF29**Previous Number:** ABMT-GEN-037 REV01**Change Number:** ABMT-CCR-335

Transplant Center Training: Receive & Store

SCOPE

The scope of this document is the Commercial Licensed Omisirge® (omidubicel-only) product handling, to include receipt, handling, storage, chain of custody and chain of identity tracking of product at the Transplant Center.

This document is to be used internally by Gamida Cell employees and externally by Transplant Center staff.

Clinical investigational products are out of scope.

Please Note: Images in this presentation may not portray actual equipment or materials. They are provided as examples to provide context to this training.

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Definitions and Acronyms

¹Definitions are customized for the Omisirge® process at Gamida Cell.

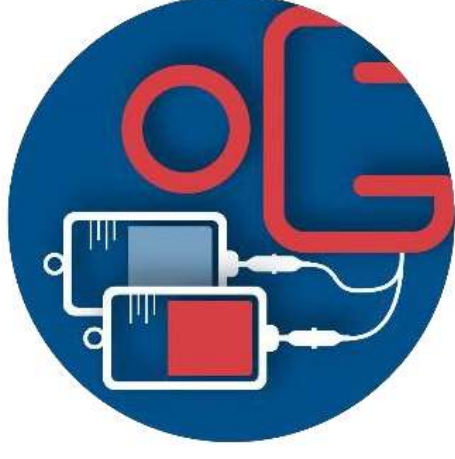
Term	Definition
CBB	Cord Blood Bank
Chain of Custody (COC) ¹	Linking the sequential events that confirm the COC at each movement and human transfer of the raw cord blood material or final product per SOPs and electronic systems.
Chain of Identity (COI) ¹	Linkage of the patient to the CBU and to the product – connecting the Gamida Cell Patient ID number and CBU ID to the Manufacturing Batch number.
Cord Blood Unit (CBU) ¹	Selection of cord blood unit for transplantation involves combining both cell dose and HLA (human leukocyte antigens) matching as independent yet overlapping variables. Cell dose and cell yield at the time of transplant are critical given that the transplants are being performed with minimal cells for reliable engraftment.
Enterprise resource-planning (ERP) ¹	A system consisting of a suite of business applications used for manufacturing, supply chain, financial and quality business process flow transactions.
Gamida Cell Assist (GCA) ¹	A customer relationship management system from salesforce.com that manages patient information for the purposes of patient registration, enrollment, and cell order management by use of hospital portal, case tracking system, and supply chain management system. This also includes the team of case managers to manage the orders.
Mfg	Manufacturing
BeTheMatch® MatchSource® ¹	Database utilized to order material for Omisirge®.
SOP	Standard Operating Procedures

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BACKGROUND

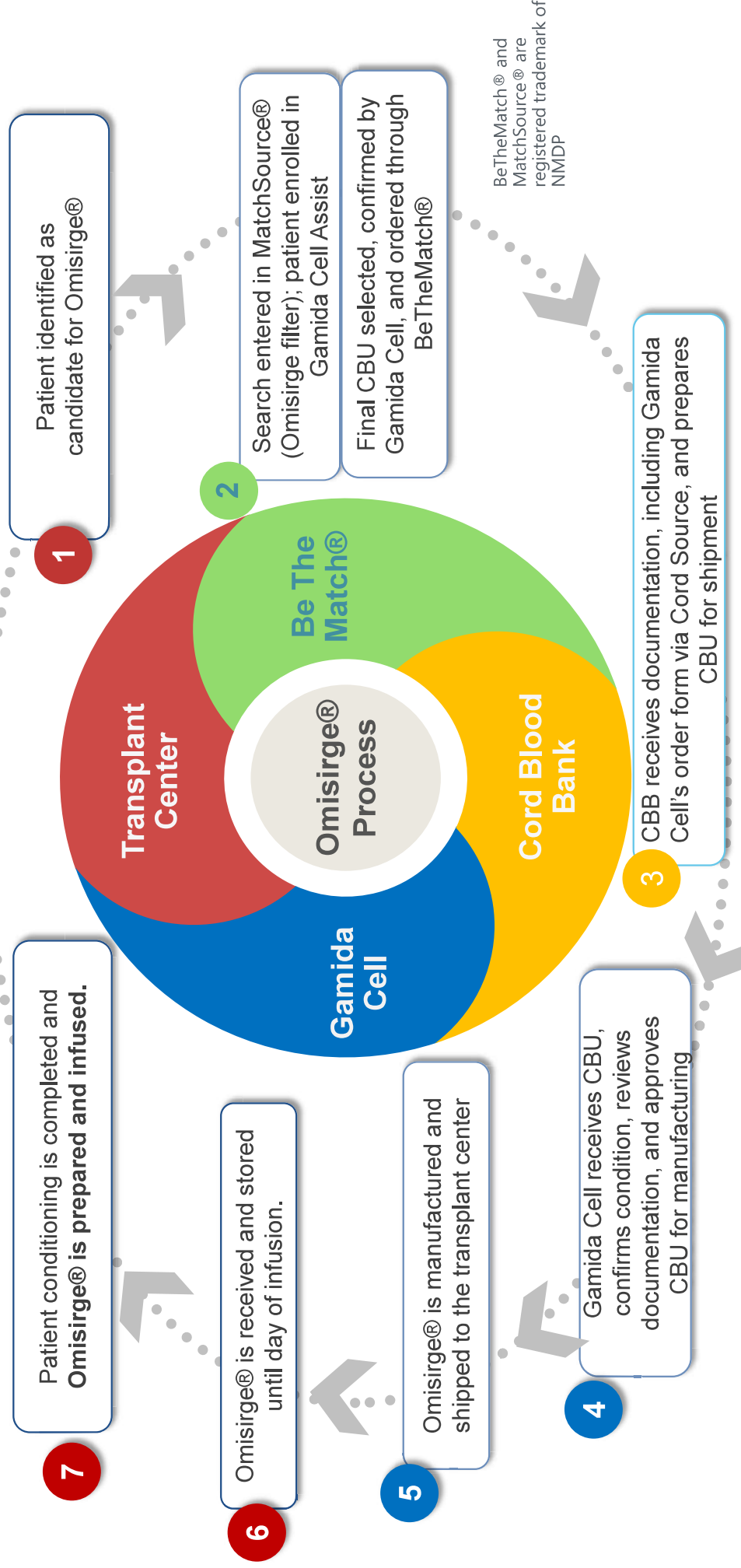
What is Omisirge?

OMISIRGE is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood



- CF** allogeneic, hematopoietic CD34+ progenitor cells and other cell populations, including more differentiated myelomonocytic cells, dendritic cells and granulocytes
- NF** allogeneic, hematopoietic mature myeloid & lymphoid cells
- IS** two Infusion Solution (IS) bags (8% w/v HSA and 6.8% w/v Dextran 40 in 0.9% Sodium Chloride) are also provided for diluting each fraction after thawing, one specifically for the CF and one specifically for the NF

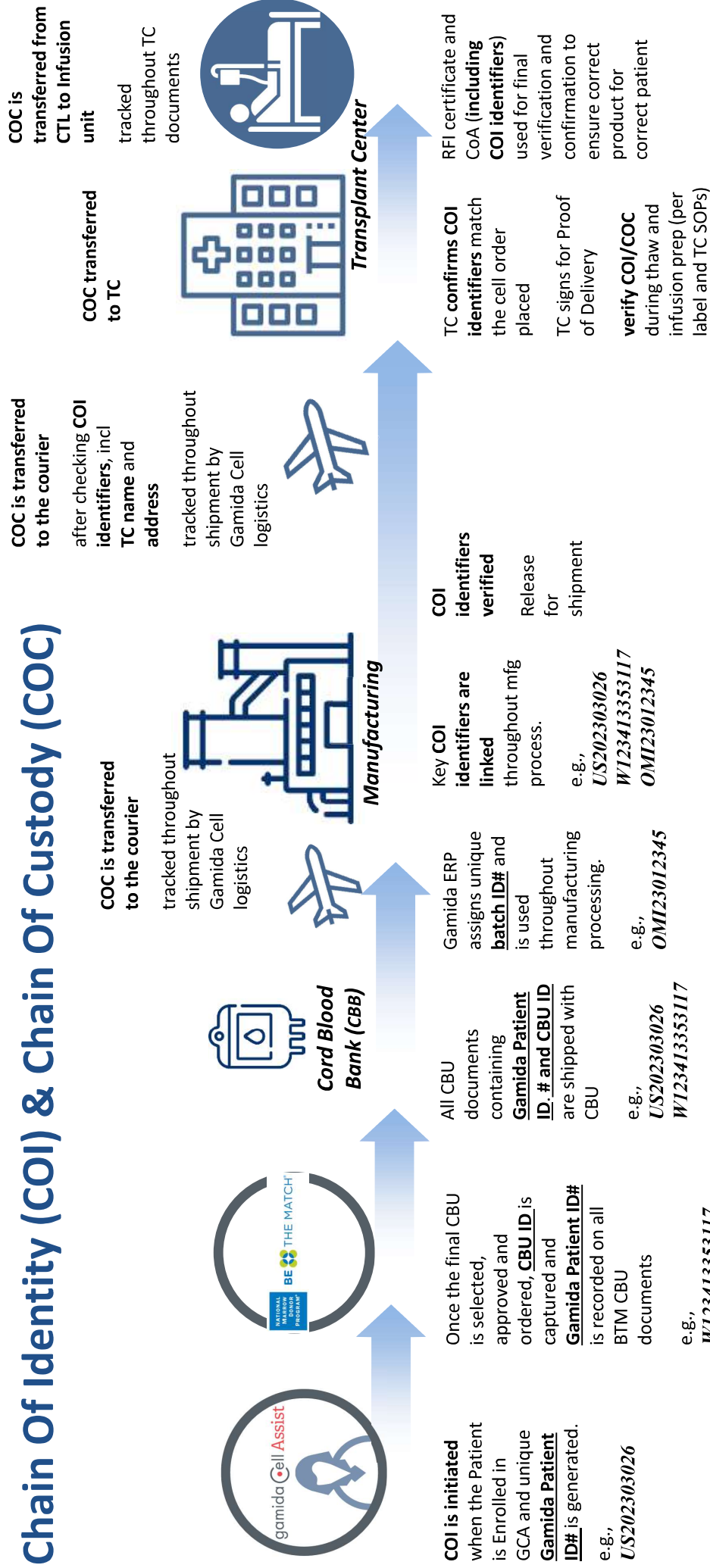
- The patient's identity must match the patient-specific identifiers on all product and shipment labels throughout the process
- Do NOT infuse Omisirge if the information on the product and shipment labels do not match the intended patient
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• See Full Prescribing Information including Boxed Warning available at this presentation or at [Omisirge.com](https://www.omisirge.com)

TRAINING -- Module 3 Transplant Center Receive and Ship

Chain Of Identity (COI) & Chain Of Custody (COC)



EQUIPMENT AND SUPPLIES

Provided By Gamida Cell

- LN2 Shipper- Vapor phase LN2 shipper consisting of a rigid exterior shell (LN2 shipper), containing LN2 dewar and metal shipping rack that holds 2 metal cassettes, containing the final product CF and NF cryopreserved bags, and the chimerism testing samples. A tamper proof serialized zip tie is attached to the dewar inside the LN2 dry vapor shipper to ensure the product is not tampered with during transit. This serialized code is listed on documentation packaged in the shipment.

- Temperature monitoring device
- Shipping and product specific documentation

- Refrigerated Shipper (single use) – temperature controlled between 2-8 °C used to ship and transport the 2 Infusion Solution (IS) bags, one for each fractioned product (CF and NF), packaged in sterile bags.
- Temperature monitoring device

- Shipments are delivered to the Transplant Center via courier
- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
- Sign proof of delivery. Courier will provide proof of delivery to Gamida Cell transferring COC to the Transplant Center



-150 °C
-15 °C



Metal Frame



2-8 °C



Infusion Solution



Infusion Solution



- Documents included with shipper; Release for Shipment Certificate, PJ Donor Determination and Summary of Records document
- Documents via GCA; CoA for the CF, NF and IS batches and Release For Infusion Certificate

TRAINING -- Module 3 Transplant Center Receive and Store **TEM00002399** Ver. 5.0

EQUIPMENT AND SUPPLIES



Supplied and Controlled by TC

- LN2 freezer with the ability to hold metal cassettes, maintaining $\leq -150^{\circ}\text{C}$ in the vapor phase
- Cryo gloves for removal of Omisirge® from liquid nitrogen (LN) shipper
- Dolly
- Controlled 2-8 $^{\circ}\text{C}$ refrigerator
- Tube Sealers
- Biosafety Cabinets (BSC)
- Alcohol wipes
- Sterile bags
- LN2 vapor phase transport vessel
- Preparation for Thawing equipment (waterbath, thermometer, timer, sterile gloves or equivalent, scissors)
- Room temperature transport vessel
- TC SOPs and Forms

- See Full Prescribing Information including Boxed Warning available at this presentation or at [Omisirge.com](https://www.omisirge.com)

LN2 Packaging Example



Liquid nitrogen dry vapor shipper



Metal Frame



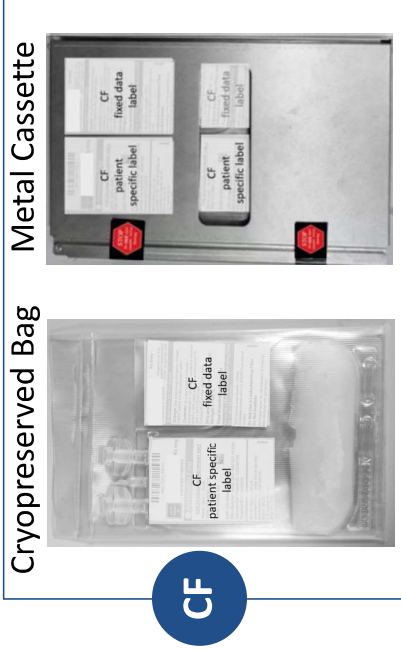
Segment in Sample Bag in Cassette



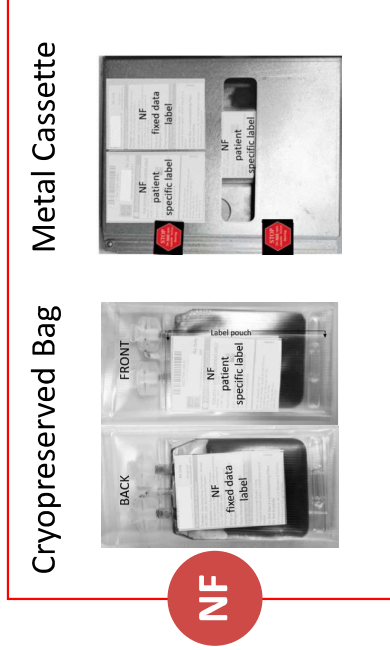
NF DP Sample in Vial



Chimerism Testing Sample



CF

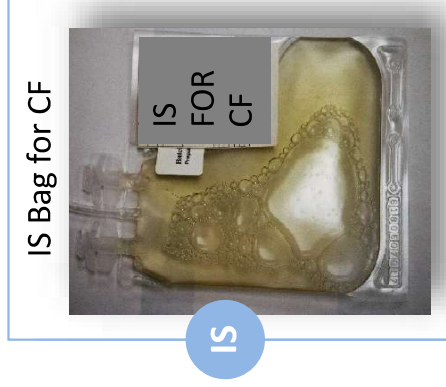


NF

IS Packaging Example

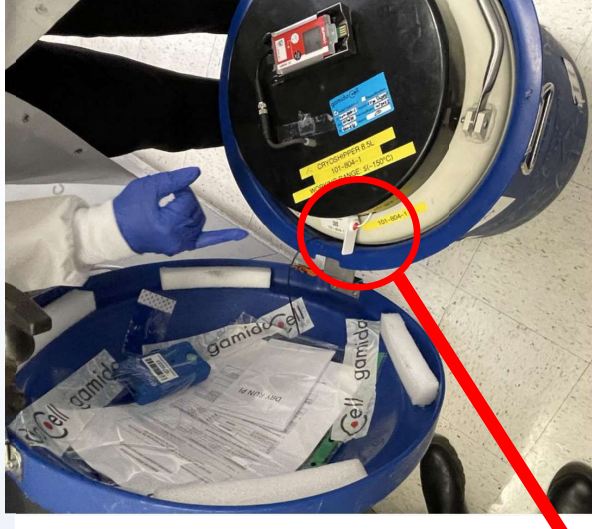


Refrigerated Shipping Container



Receiving Omisirge® shipments at your Transplant Center – LN2 Shipper (1 of 4)

- Carefully transport the LN2 shipper to an unpacking location.
 - Due to the size and weight of the LN2 shipper, it is recommended that a dolly be used when transporting the shipper. The shipper should never be laid on its side during transport.
- Verify product and patient identity on the LN2 shipping label against the TC order/patient files.
- Inspect the shipping container for evidence of damage or tampering. For any questions, **contact Gamida Cell Assist**
- Cut the zip tie on the outside of the dewar
- Open the lid of the LN2 shipper. Verify that the black dewar lid is fastened to the dewar with the serialized zip tie.
- The number on the serialized zip tie will be verified against the shipping documentation for consistency.



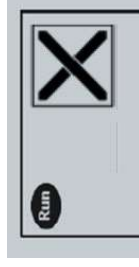
- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
- **See Full Prescribing Information including Boxed Warning available at this presentation or at Omisirge.com**

Receiving Omisirge® shipments at your Transplant Center – LN2 Shipper (2 of 4)

- Check the temperature monitoring device (1) and verify alarm status;
 - Confirm the screen displays “Run”
 - A tick mark ☒ confirms temperature within limits
- Read the temperature on the screen and document the temperature using local TC procedures and forms.
 - If an alarm is observed showing an ☒ on the display, this will indicate the temperature was out of limits.

Immediately contact Gamida Cell Assist

- Once the on the screen temperature confirmed and documented, press the STOP button to end recording of temperature



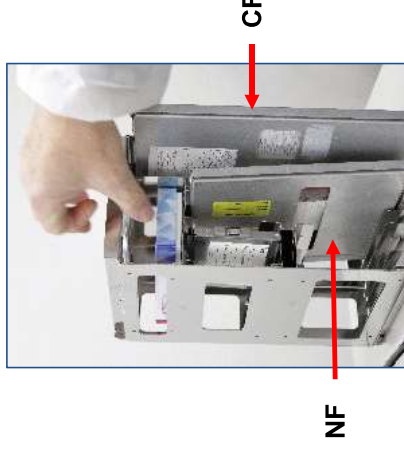
(1)



- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
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Receiving Omisirge® shipments at your Transplant Center – LN2 Shipper (3 of 4)

- Clear the unpacking location to ensure Omisirge product is not mixed with other product lots or materials.
- Remove the black lid of the LN2 dewar and remove the metal rack.
- Remove the two metal cassettes for each CF and NF product.
 - Keep the metal rack and metal cassettes over LN2 or dry ice while removing from the metal rack



Do NOT open the metal cassettes to remove the CF and NF bags until the time of thawing preparations since the product's overwrap bag may inflate preventing cassette closure.

- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
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Receiving Omisirge® shipments at your Transplant Center – LN2 Shipper (4 of 4)



- Hold the final product while inspecting over the LN2 vapor or dry ice.
- Verify that the COI and patient information on both the CF and NF cassettes match the identity of the patient with the patient-specific identifiers on the cassettes and cryopreserved bag labels (visible through the cassette window).
- If patient-specific identifiers do not match, place the cassettes back in the metal rack and back in the LN2 dewar and close the dewar with the black lid. **Immediately contact Gamida Cell Assist.**
- Verify that the products are within their expiry date by checking the “EXP” dates on the front of the metal cassettes and through the cassette windows. **Do NOT open the cassettes to locate the expiration date.** For any issues **Immediately contact Gamida Cell Assist.**

Patient Specific identifiers are visible on the cryopreserved bag through the cassette window

Patient-specific identifiers on metal cassette label:

Patient Name
Patient Date of Birth
Gamida Cell Patient ID
Hospital Patient ID

Patient-specific identifiers on cryopreserved bag label visible through metal cassette label:

Patient Name
Patient Date of Birth
Gamida Cell Patient ID
Hospital Patient ID



- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
- **See Full Prescribing Information including Boxed Warning available at this presentation or at Omisirge.com**

Storing Omisirge® CF and NF

at your Transplant Center

- Transfer the metal cassettes containing the CF and NF cryopreserved bags and the Chimerism Testing Sample(s)* and store in the vapor phase of liquid nitrogen storage at $\leq -150^{\circ}\text{C}$.
- Ensure the two cassettes and samples are stored and tracked in the selected location in the designated LN2 vapor phase freezer to prevent product mix-up.
- Verify and confirm the temperature of the LN2 vapor phase freezer is $\leq -150^{\circ}\text{C}$ at the time product is stored.
- Throughout the storage duration, the temperature monitoring should follow institutional procedures.
- Use closed containers when transporting the product within the facility

* Chimerism Testing Samples;

- CBU segment when available
- NF DP sample when no segment is available

- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
- **See Full Prescribing Information including Boxed Warning available at this presentation or at Omisirge.com**



CF

NF



Temperature-controlled liquid
nitrogen storage
($\leq -150^{\circ}\text{C}$ in the vapor phase)

Receiving Omisirge® shipments at your Transplant Center – Refrigerated Shipper (1 of 4)



-28°C

- Carefully transport the refrigerated shipper to an unpacking location.
- Verify that the products are within their expiry date by checking the “EXP” dates on the primary label. If there is an issue ***Immediately contact Gamida Cell Assist.***
- Verify and confirm the identity of the patient matches the patient-specific identifiers on the shipper label against the TC order/patient files.
- Inspect the shipping container for evidence of damage or tampering. For any questions, ***contact Gamida Cell Assist.***



- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COG
- **See Full Prescribing Information including Boxed Warning available at this presentation or at Omisirge.com**

Receiving Omisirge® shipments at your Transplant Center – Refrigerated Shipper (2 of 4)



2-8°C



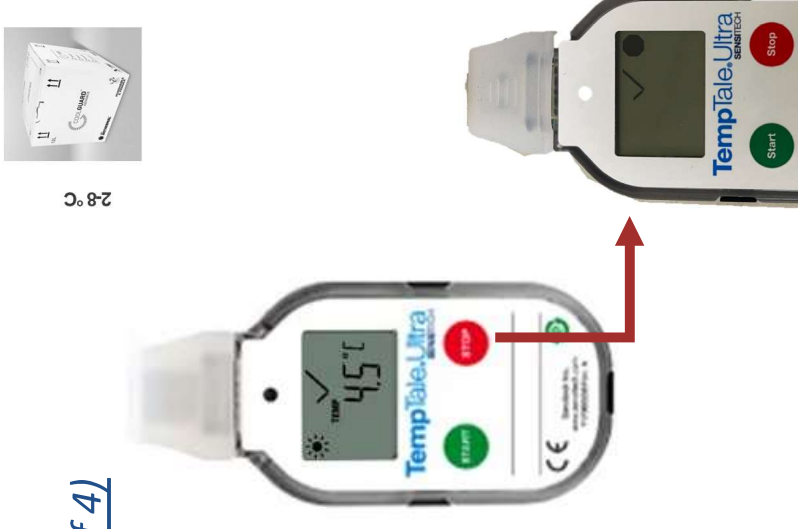
- Open the refrigerated shipper and remove top PCM (phase change material).
- Remove the inner silver container box.
- Open the silver container to access the temperature monitoring device and two Infusion Solution bags.



- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
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Receiving Omisirge® shipments at your Transplant Center – Refrigerated Shipper (3 of 4)

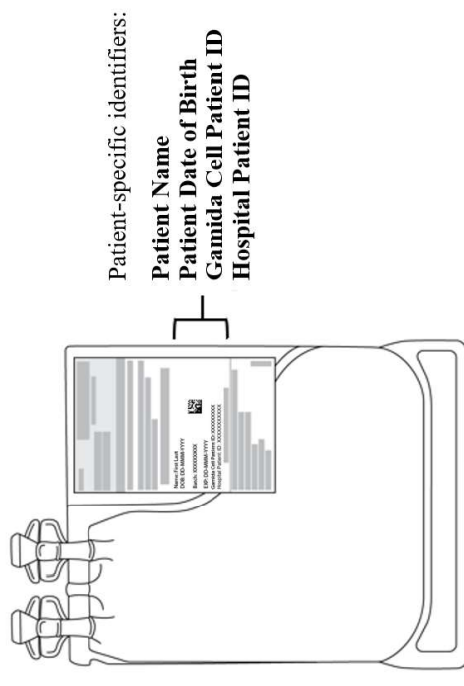
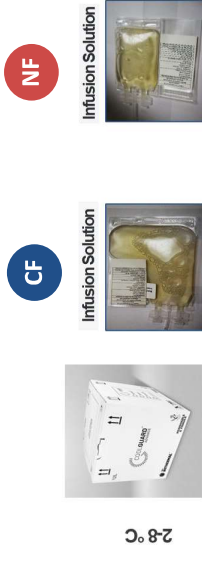
- Remove the temperature monitoring device.
- Check the temperature monitoring device (1) and verify alarm status;
 - Confirm the screen displays sun icon ☀️.
 - A tick mark ☒ confirms temperature within limits.
- Read the temperature on the screen and document the temperature using local TC procedures and forms.
 - If an alarm is observed showing an ☐ on the display, this will indicate the temperature was out of limits. **Immediately contact Gamida Cell Assist**
- Stop the TempTale by pressing the STOP button.
- Return the TempTale to the courier in empty 2-8 °C shipper. See slide 23-25



- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
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Receiving Omisirge® shipments at your Transplant Center – Refrigerated Shipper (4 of 4)

- Remove the two Infusion Solution bags.
- Verify that the products are within their expiry date by checking the “EXP” dates. For any issues **Immediately contact Gamida Cell Assist.**
- Verify and confirm the identity of the patient matches the patient-specific identifiers on the IS bag labels, against the TC order/patient files. Read the patient labels through the sterile bag.
- Verify and ensure both bags are intact and the clamp is closed on the tubing.
- If patient-specific identifiers do not match, place the bags back in the silver container and back in the refrigerated shipper. **Immediately contact Gamida Cell Assist.**



- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
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Storing Omisirge® Infusion Solution at your Transplant Center

- Transfer the two bags of IS, specified for each CF and NF, and store in a 2-8°C refrigerated storage until the time of thaw of the Omisirge® CF and NF.
- Ensure the bags are stored and tracked in a selected location in the designated refrigerator to prevent product mix-up.
- Verify and confirm the temperature of refrigerator is between 2-8 °C at the time product is stored.
- Throughout the storage duration, the temperature monitoring should follow institutional procedures.



CF



NF

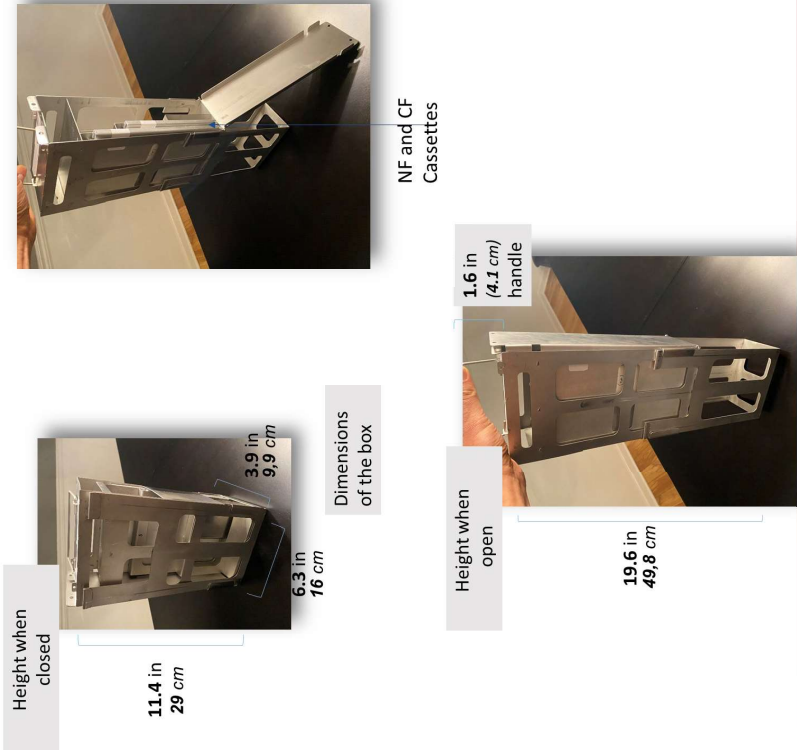
Infusion Solution

Controlled 2-8 °C Refrigerator For Infusion Solution

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REFERENCES

Metal Frame (containing CF & NF Metal Cassettes) Dimensions



CF & NF Metal Cassette Dimensions



Return of empty shipper back to Gamida Cell

Preparing return of empty LN2 and 2-8 shipper back to Gamida Cell

- Re-pack empty LN2 shipper
- Place the empty metal rack back in the dewar
- Replace the black dewar lid
- Ensure datalogger is securely attached
- Close the shipper lid



- Contact Gamida Cell Assist at 1(844) 477-7478 Case Manager to coordinate empty shipper pickup by the courier

Preparing return of empty LN2 and 2-8 shipper back to Gamida Cell

- Place the TempTale datalogger in the silver box
- Close the shipper lid

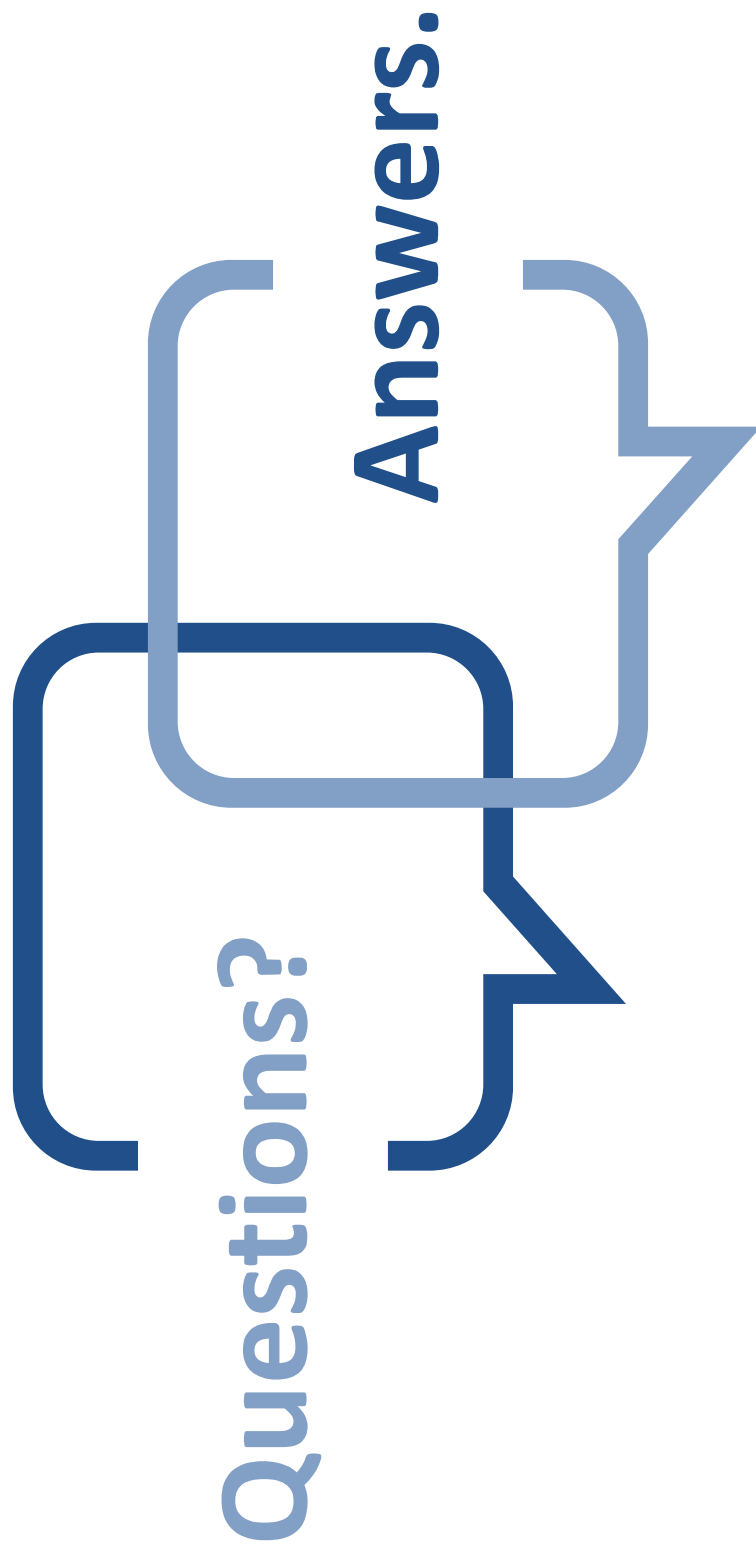


- Contact Gamida Cell Assist at 1(844) 477-7478 Case Manager to coordinate empty shipper pickup by the courier

Key Points

- 4 total bags + 1 sample will be delivered from Gamida Cell, 2 bags (CF and NF) + chimerism sample frozen in LN2 dewar and 2 bags (IS for CF and IS for NF) in 2-8°C Single use packaging
- Have dedicated area for unpacking material, clear of other products to avoid error.
- **Verify Patient Information** when handling packaging and final products
- **Do NOT** open CF or NF final product metal cassettes
- Use secondary transport containers when moving product
- Ensure internal storage equipment is at temperature
 - CF and NF are stored in LN2
 - IS for CF and IS for NF are stored at 2-8°C
- Courier will pick-up LN2 dewar with metal rack and temperature data loggers, and empty 2-8°C shipper with temperature data logger
- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
- Follow any procedures established by your Transplant Center to manage COI/COC
- Reference 03.031-Appendix 1 for Roles and Responsibilities

Q&A



CHANGE HISTORY

Description of Change	Rationale of Revision
1. Sun icon on slide 18 to be moved 2.Slide 18- additional picture of temptale to add 3. Slide 19- add to check the labels through the sterile bag. Add check clamp is closed. 4. Slide 26- update key points to remove bullet "inspect each packaging component for integrity and conditions were met"	1. formatting fix 2. supporting visual aid 3. additional clarification so sites do not open Infusion Solution sterile bags 4. Contradicts the ask to not open the metal cassette for receiving product.

Signature Manifest**Document Number:** ABMT-GEN-037**Revision:** 02**Title:** Gamida Cell: Transplant Center Receive and Store**Effective Date:** 30 Jan 2024

All dates and times are in Eastern Time.

ABMT-GEN-037 Gamida Cell: Transplant Center Receive and Store**Author**

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		16 Jan 2024, 03:15:49 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		16 Jan 2024, 03:16:32 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		16 Jan 2024, 03:30:22 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)	Associate Director, Quality Assurance	18 Jan 2024, 12:38:16 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	19 Jan 2024, 05:16:13 PM	Approved