



Division of Cellular Therapy

DOCUMENT NUMBER: ABMT-GEN-036**DOCUMENT TITLE:**

Gamida Cell: Transplant Center Training: Thawing & Preparation to Infuse

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-036 REV01**Change Number:** ABMT-CCR-334



Transplant Center Training: Thaw & Preparation to Infuse

InfoCard #: ABMT-GEN-036 Rev. 02 Effective Date: 30 Jan 2024

TRAINING -- Module 4 Transplant Center Thaw and Preparation to Infuse
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SCOPE

The scope of this document is the Commercial Licensed Omisirge® (omidubicel-only) product handling, to include thawing, preparing for infusion, 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.

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

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 units 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

See Full Prescribing Information including Boxed Warnings at Omisirge.com

BACKGROUND

What is Omisirge®?

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

CF

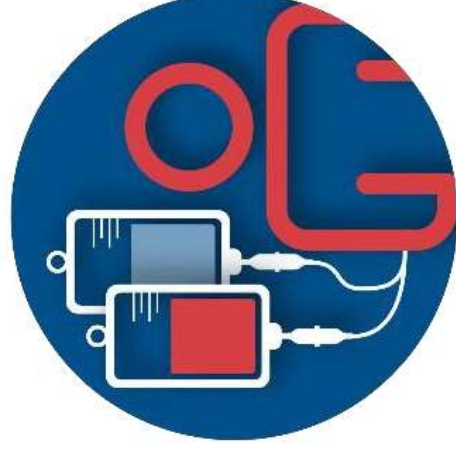
allogeneic, hematopoietic CD34+ progenitor cells and other cell populations, including more differentiated myelomonocytic cells, dendritic cells and granulocytes

NF

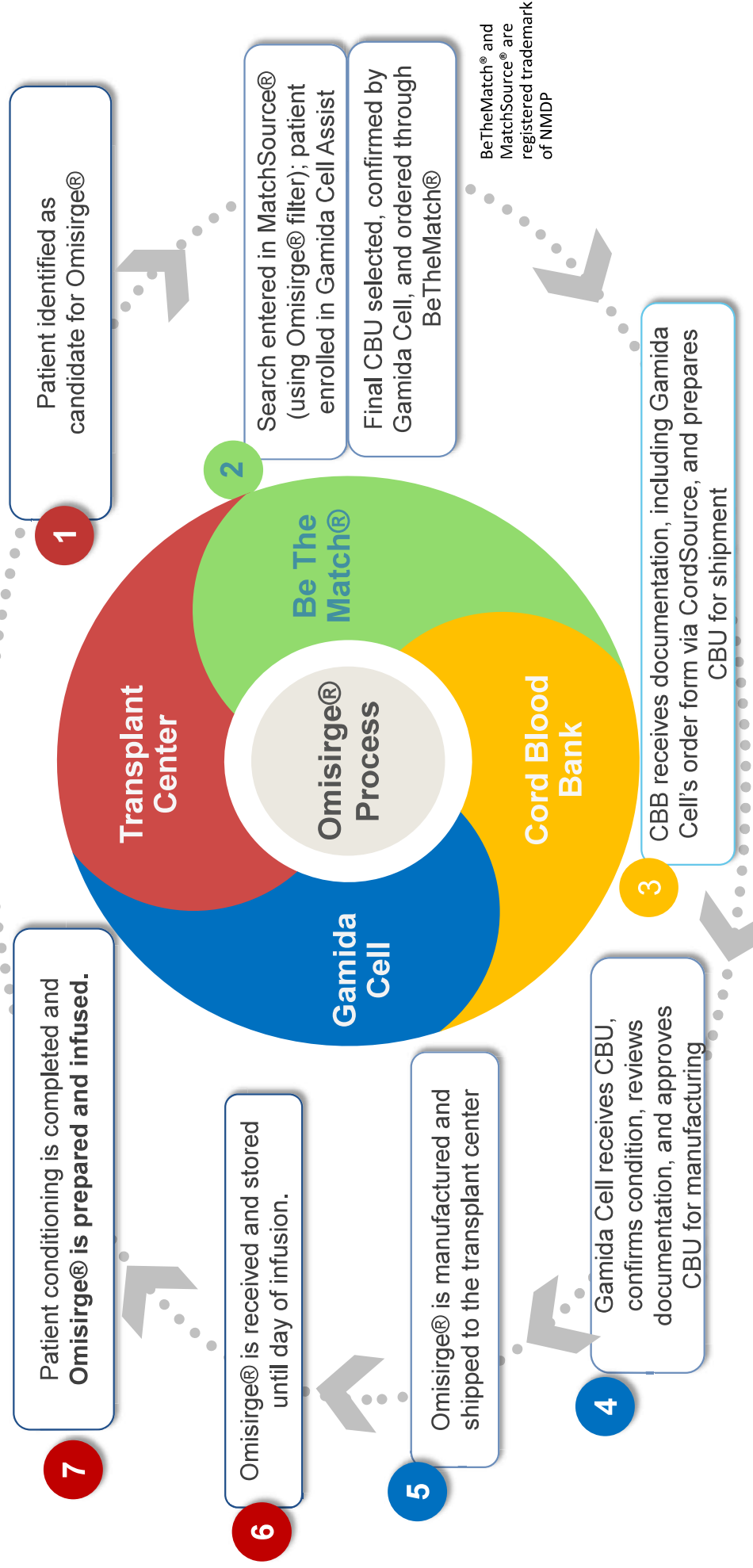
allogeneic, hematopoietic mature myeloid & lymphoid cells

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

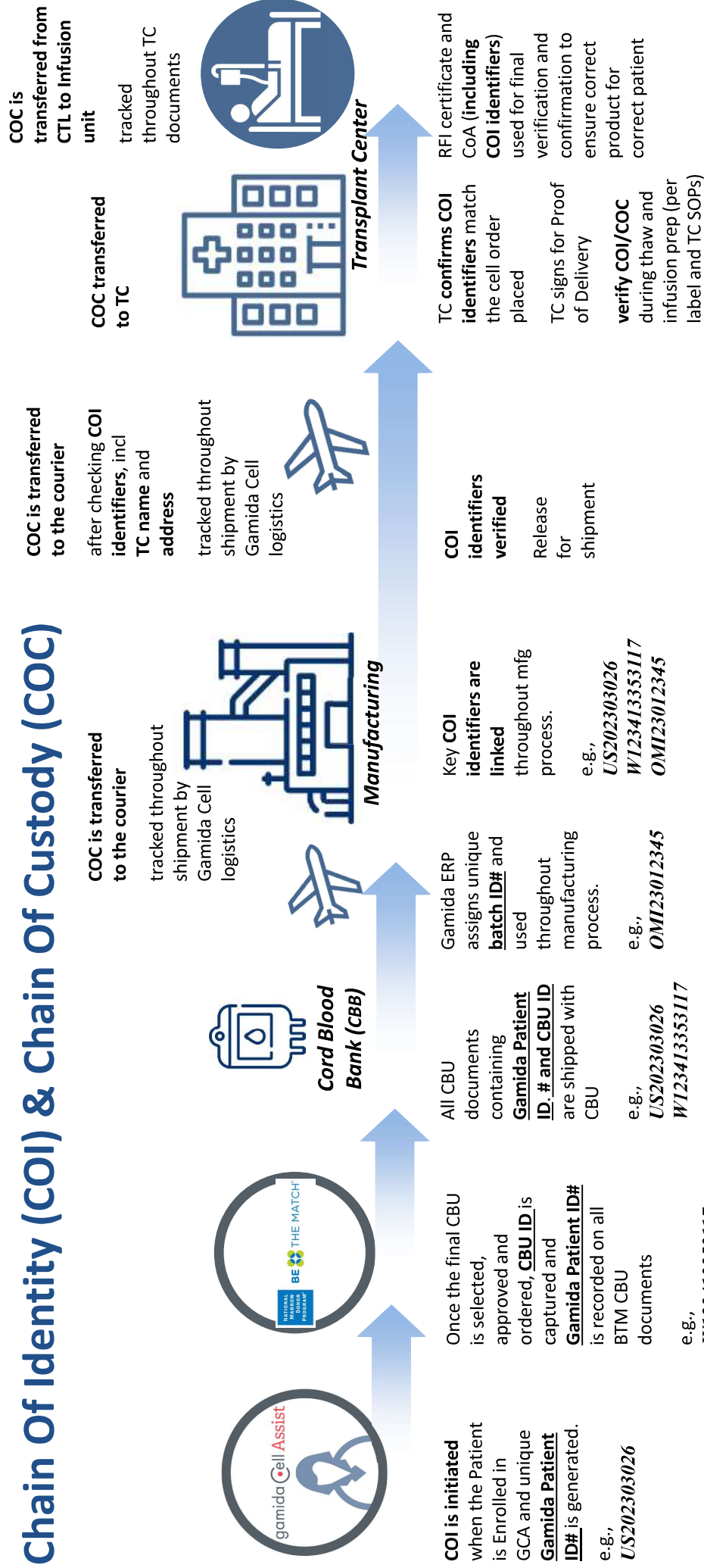


- The patient's identity must match the patient-specific identifiers on all product and shipment labels throughout the process
- Do NOT infuse Omisirge® if the information on the product and shipment labels do not match the intended patient
- **See Full Prescribing Information including Boxed Warning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



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

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



Planning prior to Treatment Preparation- Release for Infusion

- Conditioning of the patient should not be started until receipt of the the Release for Infusion (RFI) certificate, from Gamida Cell for all patient-specific batches.
- The Release for Shipment and Release for Infusion (RFI), for each patient specific batch, include the Certificates of Analysis (CoA) for the CF, NF and IS batches.
- The RFI certificate will be issued via Gamida Cell Assist Hospital Portal up to 72 hours after completion of manufacturing.

1

gamidaCell Assist



Username



Password

Login

[Forgot Password?](#)

2

gamidaCell Assist

Home

Register New Patient

My Patients

Resources

3

gamidaCell Assist

Home

Pending Patients

Active Patients

Completed Patients

4

James, Reese Z.
DOB: 8/16/1999
Gamida Patient ID: US202303021
Hospital Patient ID: F12345432119873

3/27/2023

Patient Enrolled

CBU Shipped

03/28/2023

CBU Delivered

03/28/2023

MFG Begins

Released to Ship

FP Delivered

Released to Infuse

Release Documents

Infusion Certificate

5

ACTION	DOCUMENT NAME
View	Release for Infusion

[Close](#)

Gamida Cell Assist- Registered Portal User

1. Login to GCA or ask a registered user to download the certificates.
<https://gamidacellassist.force.com/>
2. After logging in, navigate to 'My Patients'.
3. Under 'My Patients' go to 'Active Patient Tab'. List will be current patients with a tracker showing steps completed up until Release for Infusion.
4. Patient name, DOB, Gamida Patient ID, and Hospital Patient ID will be shown to ensure COI.
5. When the documents are ready to view, the tracker will enable the Release document and the Release to Infuse link (turns from grey to blue).
 - Click the document, a new window will display with the option to view. Select View, the document will download to your browser, click on the download to review and print the document.

Planning prior to Omisirge® preparation - Release for Infusion

- Omisirge® should not be prepared until after receipt of the RFI.
- Verify and confirm receipt of the RFI Certificate and CoAs. The RFI certificate should be available around the time of product delivery at the Transplant Center and will be available in the GCA Portal (along with CoAs). Work with designated transplant center personnel to download documentation from GCA Portal
- Verify and confirm patient-specific identifiers on the RFI Certificate and CoAs match patient's identity, for final confirmation that the COI identifiers match across the RFI certificate, CoAs, omisirge® product labels
- Final CF CoA issued upon receipt of additional CF results (i.e sterility, Harvest Day CFU) typically after infusion
- The Transplant Center should attach all documents to the patient's hospital records (CoA for the CF, NF and IS batches, RFI Certificate, final CF CoA) along with all chain of identity verification and chain of custody handoff.

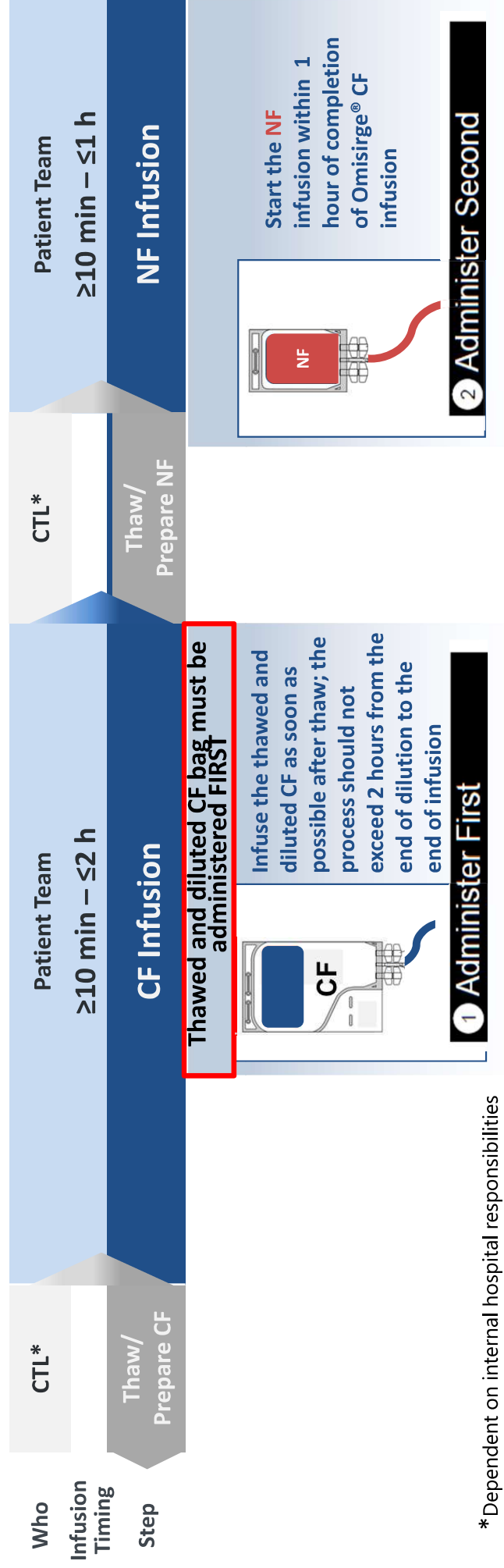


DO NOT infuse the product if the information on the patient-specific label does not match the intended patient and the RFI is not issued yet

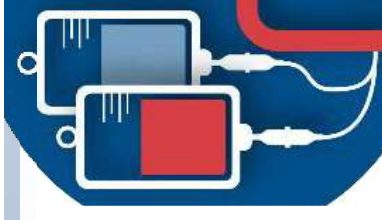
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Preparing for Omisirge® infusion – Planning Overview

Confirm the infusion time in advance and adjust the start time of CF cryopreserved bag thaw so that it will be available for infusion when the patient is ready.



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



Preparing for Omisirge® infusion - Overview

The CF bag must be administered **FIRST**

Confirm the infusion time in advance and adjust the start time of CF cryopreserved bag thaw so that it will be available for infusion when the patient is ready.

1 Administer First

- CF**
- Once the CF cryopreserved bag is removed from the metal cassette, thawing and dilution must be carried to completion and the cells administered **within 2 hours post-dilution**.

2 Administer Second

- NF**
- Do not thaw the NF cryopreserved bag until you have determined that the CF has been safely administered.
 - Once the NF cryopreserved bag is removed from the metal cassette, thawing and dilution must be carried to completion and the cells administered **within 1 hour post-dilution**.
 - The infusion of the NF bag should **begin within 1 hour after completion of the CF infusion**.

- Follow universal precautions and local biosafety guidelines for handling and disposal of human cells to avoid potential transmission of infectious diseases.
- Use aseptic technique for all processing steps, including spiking of all transfusion infusion bag ports. No samples should be drawn from Omisirge®.
- See **Full Prescribing Information including Boxed Warning available at this presentation or at Omisirge.com**

1 Administer First

CF Infusion Solution Preparation for CF

Follow universal precautions and local biosafety guidelines for handling and disposal of human cells to avoid potential transmission of infectious diseases. Use aseptic technique for all processing steps, including spiking of all transfusion infusion bag ports. No samples should be drawn from Omisirge®.

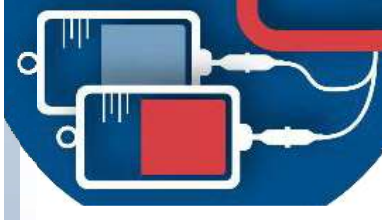
1. Remove the Infusion Solution for CF bag from the 2-8°C storage location. **Remove only the Infusion Solution for CF bag at this time.**
2. Confirm and document patient-specific identifiers on the label of the Infusion Solution for CF match the intended patient.
3. Wipe the Infusion Solution for CF sterile bag with 70% alcohol. Place it in the Biological Safety Cabinet (BSC) (if available), for **at least 20 minutes and no more than 24 hours at room temperature.** Document the start and end time of room temperature incubation for the IS for CF.

Note: Prepare equipment for thawing, including, waterbath, thermometer, timer, sterile gloves, scissors, sealer, alcohol wipes etc.). Ensure that the water batch is at an approximately 37°C, ready for step 12

4. Prior to dilution, remove the Infusion Solution for CF bag from its sterile bag. Check that the pinch clamp is closed.
5. Remove the CF metal cassette from the LN2 storage



- 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**



Preparation for Thawing the CF

The CF bag must be administered **FIRST**

CF

1 Administer First

Confirm the infusion time in advance and adjust the start time of CF cryopreserved bag thaw so that it will be available for infusion when the patient is ready.

6. Prior to opening the CF metal cassette, verify and document that the patient-specific identifiers on the label on the outside of the cassette and on the CF cryopreserved bag (visible through the cassette window) match the intended patient

7. Once patient identity has been verified, open the CF cassette and remove the CF cryopreserved bag from the cassette. Leave the CF cryopreserved bag in the overwrap bag during thawing and dilution.

8. Visually inspect and document the CF cryopreserved bag for damage, such as integrity of bag, cracks, tears and broken ports. If the bag is damaged, contact **Gamida Cell Assist**

- The cryopreserved **CF should be white in color.**
- Document the color of CF final product.

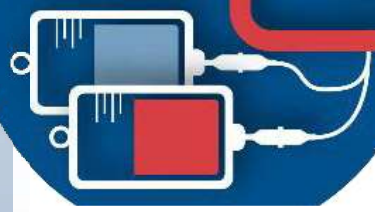
9. Once the CF cryopreserved bag is removed from the metal cassette, the thaw and dilution must be carried to completion and the cells administered **within 2 hours post-dilution.**

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Verify Patient ID





Incubate and Thawing the CF

The CF bag must be administered **FIRST**

CF

1 Administer First

Confirm the infusion time in advance and adjust the start time of CF cryopreserved bag thaw so that it will be available for infusion when the patient is ready.

10. Incubate the CF cryopreserved bag for 5 minutes at room temperature. Document the waterbath temperature per internal procedures just before thaw and document start and end of the incubation for CF.

- Verify the Patient information on the IS for CF and cryopreserved CF bag match.

11. Place the CF cryopreserved bag in an approximately 37°C waterbath until the product reaches a liquid consistency. This generally takes about 3-8 minutes.

Do not massage, knead or apply pressure on the product bag. Keep the bag fully submerged until thawed – do not remove before thawing completion. For any damaged or compromised bags during thaw; follow institutional procedures.

12. Remove the thawed bag from the waterbath as soon as the cells have completely thawed.

Do not remove the overwrap bag.

13. Wipe the overwrap with 70% alcohol. Put the bag into the BSC (if available).

14. Open the overwrap as follows:

- Wipe a pair of clean scissors with 70% alcohol.
- Cut the sealed area at the top of the overwrap.

Be careful not to damage the CF bag or the CF bag's ports/ tubing.



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• 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 [omisurge.com](https://www.omisurge.com)

Diluting the CF with IS

The CF bag must be administered **FIRST**

CF

1 Administer First

Confirm the infusion time in advance and adjust the start time of CF cryopreserved bag thaw so that it will be available for infusion when the patient is ready.

15. Insert the spike adapter attached to the Infusion Solution for CF bag into one of the ports of the CF bag, while it remains in the overwrap bag.

16. Open the pinch clamp on the Infusion Solution tubing and double the volume of the CF by adding Infusion Solution for CF (approximately 20 mL) to the CF bag. Gently swirl the bag until mixed well.

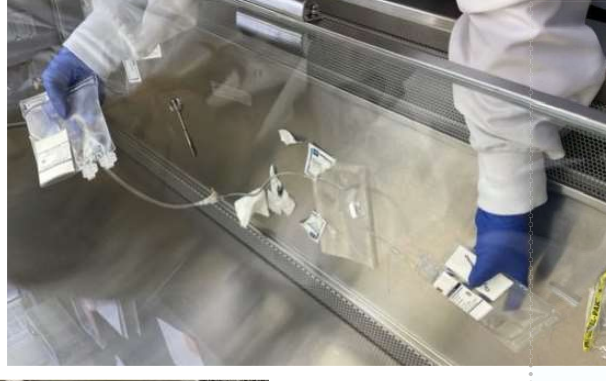
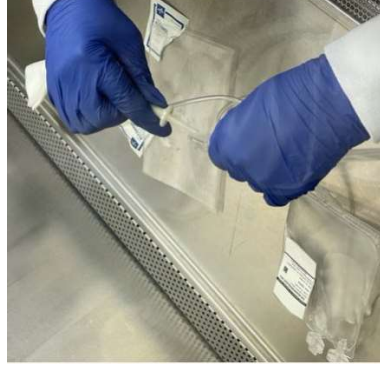
17. Add the remaining Infusion Solution for CF (approximately 60 mL) to the CF bag. Close the valve and swirl gently. Document the end time the CF bag was diluted.

18. Remove the overwrap of the CF bag and check the integrity of the CF bag.

19. Check the appearance of the contents of the CF bag.

- The thawed and **diluted CF should appear as a yellowish suspension**, essentially free of visible white clumps and foreign particulates.
- Document the diluted CF color and that it is free of white clumps and foreign particulates.

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Handoff the Diluted the CF

The CF bag must be administered FIRST

CF

1 Administer First

Confirm the infusion time in advance and adjust the start time of CF cryopreserved bag thaw so that it will be available for infusion when the patient is ready.

20. Inspect the contents of the thawed and diluted CF bag for any visible cell clumps. If visible cell clumps remain, gently invert and/or massage the bag with fingertips. Small clumps of cellular material should disperse with gentle manual mixing. **Do not infuse the CF if clumps are not dispersed, the bag is damaged or leaking, or otherwise appears to be compromised.** If this occurs, contact *Gamida Cell Assist*.
21. Heat seal and detach the emptied Infusion Solution for CF bag.
22. Connect the Transfusion Infusion Set to the free port on the CF bag.

Note: Alternately, the infusion set may be connected in accordance with internal procedures.

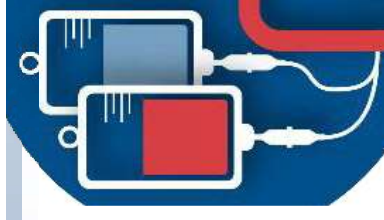
23. Place the CF bag containing the thawed and diluted CF in a new sterile bag.

Note: Do not wash, spin down, and/or resuspend CF in new media prior to infusion.

24. Transport the product to the patient at room temperature. Unless prepared at the patient's bedside, transport the product to the bedside in a temperature controlled closed box/bag to protect the product during transport.
 - Document hand-off and verification of patient's information before infusion per institutional procedures.
 - The CF bag should be **completely infused within 2 hours post-dilution**.

25. See the 'OMISIRGE® Administration' section on how to infuse the CF.

- 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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Infusion Solution Preparation for NF

NF

2 Administer Second

Follow universal precautions and local biosafety guidelines for handling and disposal of human cells to avoid potential transmission of infectious diseases. Use aseptic technique for all processing steps, including spiking of all transfusion infusion bag ports. No samples should be drawn from Omisirge®.

1. Remove the Infusion Solution for NF bag from the 2-8°C storage location.
2. Confirm and document patient-specific identifiers on the label of the Infusion Solution for NF match the intended patient.
3. Wipe the Infusion Solution for NF sterile bag with 70% alcohol. Place it in the Biological Safety Cabinet (BSC) (if available), for at least 20 minutes, and no more than 24 hours at room temperature. Document the start and end time of room temperature incubation for the IS for NF.

Note: Prepare equipment for thawing, including, waterbath, thermometer, timer, sterile gloves, scissors, sealer, alcohol wipes etc.) Ensure that the waterbath is at an approximately 37°C, ready for step 12

4. Prior to dilution, remove the Infusion Solution for NF bag from its sterile bag. Check that the pinch clamp is closed.
5. Remove the NF metal cassette from the LN2 storage

Verify
Patient
ID



- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
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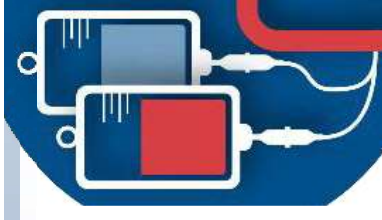
Preparation for Thawing the NF



2 Administer Second

6. Prior to opening the NF metal cassette, verify that the patient-specific identifiers on the label on the outside of the cassette and on the NF cryopreserved bag (visible through the cassette window) match the intended patient
7. Once patient identity has been verified, open the NF cassette and remove the NF cryopreserved bag from the cassette. Leave the NF cryopreserved bag in the overwrap bag during thawing and dilution.

Verify Patient ID
8. Visually inspect the NF cryopreserved bag for damage, such as integrity of bag, cracks, tears and broken ports. If the bag is damaged, contact **Gamida Cell Assist**
 - The cryopreserved **NF should be red in color**.
 - Document the color of the NF final product.
9. Once the NF cryopreserved bag is removed from the metal cassette, the thaw and dilution must be carried to completion and the cells administered **within 1 hour post-dilution**.



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Incubate and Thawing the NF

NF

2 Administer Second

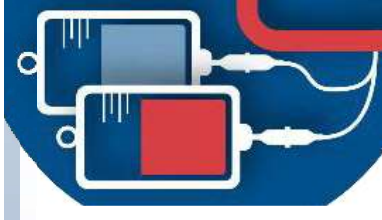
10. Incubate the NF cryopreserved bag for 5 minutes at room temperature. Document the waterbath temperature per internal procedures just before thaw and document start and end of the incubation for NF
 - Verify the Patient information on the IS for NF and cryopreserved NF bag matches
11. Place the NF cryopreserved bag in an **approximately 37°C** waterbath until the product reaches a liquid consistency. This generally takes about 3-8 minutes.

Do not massage, knead or apply pressure on the product bag. Keep the bag fully submerged until thawed – do not remove before thawing completion. For any damaged or compromised bags during thaw; follow institutional procedures.

12. Remove the thawed bag from the waterbath as soon as the cells have completely thawed. **Do not remove the overwrap bag.**
13. Wipe the overwrap with 70% alcohol. Put the bag into the BSC (if available).
14. Open the overwrap as follows:
 - Wipe a pair of clean scissors with 70% alcohol.
 - Cut the sealed area at the top of the overwrap.

Be careful not to damage the NF bag or the NF bag's ports/ tubing.

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Diluting the NF with IS

NF

2 Administer Second

15. Insert the spike adapter attached to the Infusion Solution for NF bag into one of the ports of the NF bag, while it remains in the overwrap bag.
16. Open the pinch clamp on the Infusion Solution tubing and double the volume of the NF by adding Infusion Solution for NF (approximately 10 mL) to the NF bag. Gently swirl the bag until mixed well.
17. Add the remaining Infusion Solution for NF (approximately 30 mL) to the NF bag. Close the valve and swirl gently. Document the end time the NF bag was diluted.
18. Remove the overwrap of the NF bag and check the integrity of the NF bag.
19. Check the appearance of the contents of the NF bag.
 - The thawed and **diluted NF should appear as a reddish suspension**, essentially free of visible clumps and foreign particulates.
 - Document the diluted NF color and that it is free of visible clumps and foreign particulates.



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Handoff the Diluted NF

NF

2 Administer Second

20. Inspect the contents of the thawed and diluted NF bag for any visible cell clumps. If visible cell clumps remain, gently invert and/or massage the bag with fingertips. Small clumps of cellular material should disperse with gentle manual mixing. **Do not infuse the NF if clumps are not dispersed, the bag is damaged or leaking, or otherwise appears to be compromised.** If this occurs, contact ***Gamida Cell Assist.***

21. Heat seal and detach the emptied Infusion Solution for NF bag.

22. Connect the Transfusion Infusion Set to the free port on the NF bag.

Note: Alternately, the infusion set may be connected in accordance with internal procedures.

23. Place the NF bag containing the thawed and diluted NF in a new sterile bag.

Note: Do not wash, spin down, and/or resuspend NF in new media prior to infusion.

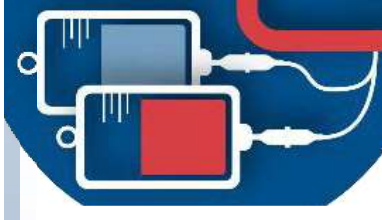
24. Transport the product to the patient at room temperature. Unless prepared at the patient's bedside, transport the product to the bedside in a temperature controlled closed box/bag to protect the product during transport.

- Document handoff and verification of patient's information before infusion per institutional procedures.

- The NF bag should be **completely infused within 1 hour post-dilution.**

25. See the '**OMISIRGE Administration**' section on how to infuse the NF.

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Omisirge® Administration

Follow universal precautions and local biosafety guidelines for handling and disposal of human cells to avoid potential transmission of infectious diseases.

- Do NOT use a leukodepleting filter
- Central venous access is recommended for the infusion of Omisirge®.
- Confirm that the patient's identity matches the patient-specific identifiers on the CF and NF bags.
- Administer Omisirge® by gravity infusion.
- Prior to spiking both the CF and NF bags, prime the infusion set tubing with normal saline.
- **Infuse the entire contents** of the CF and NF bags.
 - The thawed and diluted CF bag must be infused FIRST. The infusion time should not exceed 2 hours from the end of dilution to the end of CF infusion. Should an infusion reaction occur, appropriately manage the reaction before thawing the NF.
 - The thawed and diluted NF is infused within 1 hour of safely administering the CF infusion. The infusion time should not exceed 1 hour from the end of dilution to the end of infusion
- **The rate of infusion should not exceed a maximum of 10 mL per kg per hour.**
- After the entire contents of the CF and NF bags are each infused, wash the tubing with normal saline at the same infusion rate to ensure as many cells as possible are delivered to the patient.
- In the event of any deviation from the dosing schedule, contact Gamida Cell at (844) 477-7478.

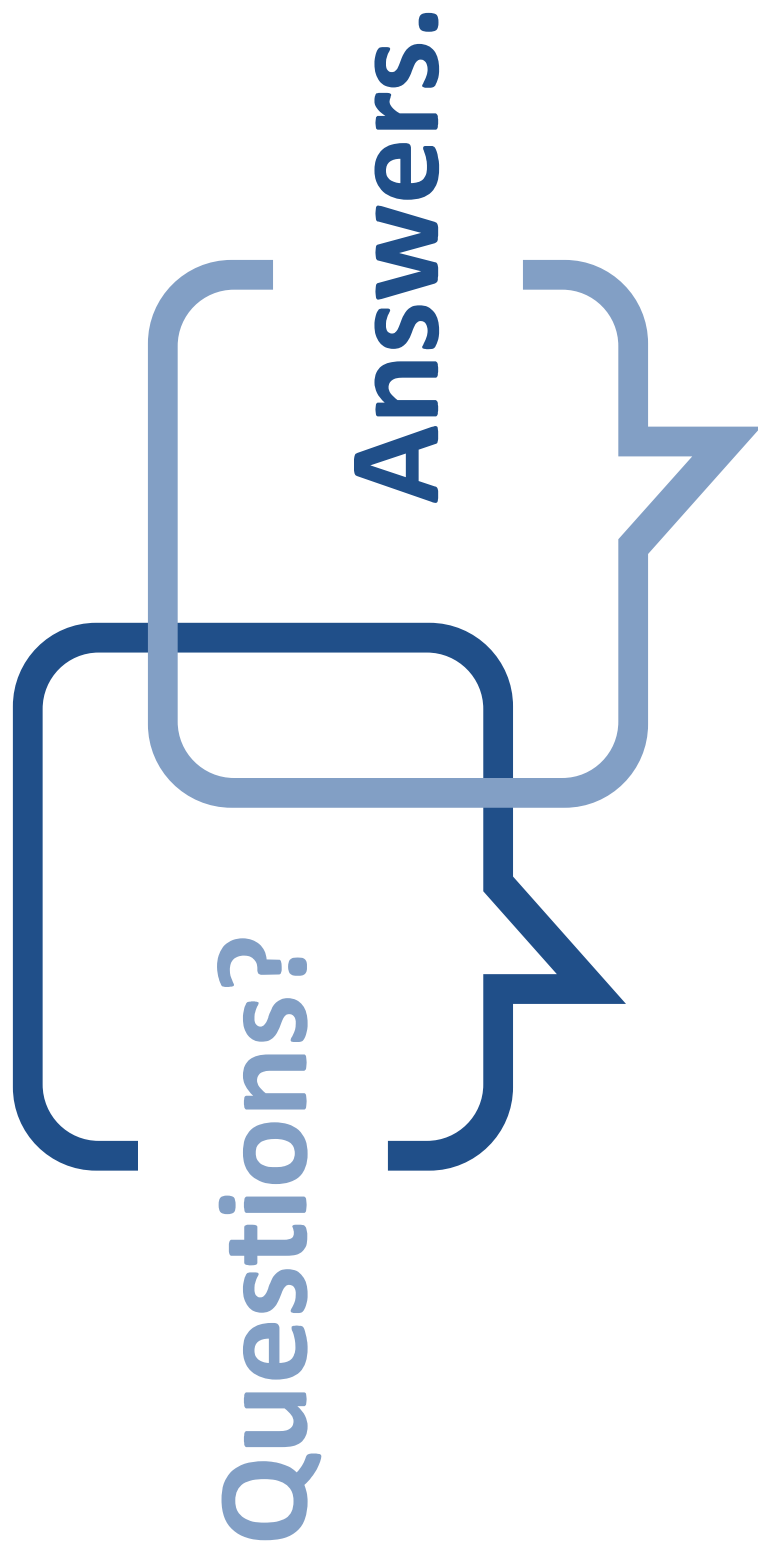


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Key Points

- 4 total bags will be utilized for the treatment of the patient, 2 frozen cellular bags (CF and NF) and 2 refrigerated bags (IS for CF and IS for NF).
 - Plan the timing for treatment accordingly and verify all paperwork required is available.
 - Verify Patient Specific Information before proceeding
 - IS for CF dilutes the CF bag, IS for NF dilutes the NF bag
 - Entire contents of CF infusion will be administered first
 - Must be infused within 2 hours post thawing and end of dilution of CF
 - Entire contents of NF infusion will be administered second and within 1 hr of CF safely being administered.
 - The infusion time should not exceed 1 hour from the end of dilution to the end of infusion
 - Do **NOT** use a leukodepleting filter
 - Reference 03.031-Appendix 1 for Roles and Responsibilities
- If there are any issues, concerns or questions, contact **Gamida Cell Assist at 1(844) 477-7478**
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Q&A



CHANGE HISTORY

Description of Change	Rationale of Revision
- Slide 7- repetitive wording remove bullet 1 "Certificate of Analysis for the CF..." covered in bullet - Slide 17- remove The in tittle - Slide 18- Change Batch to Bath - Slide 20- Change CF to NF - Slide 24- Change NF bullet to match PI wording exactly	1-4 grammar clarification or minor correction to slides. 5. Clarification based on PI

Signature Manifest**Document Number:** ABMT-GEN-036**Revision:** 02**Title:** Gamida Cell: Transplant Center Training: Thawing & Preparation to Infuse**Effective Date:** 30 Jan 2024

All dates and times are in Eastern Time.

ABMT-GEN-036 Gamida Cell: Transplant Center Training: Thawing & Preparation to Infuse**Author**

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		16 Jan 2024, 03:18:14 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		16 Jan 2024, 03:18:43 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		16 Jan 2024, 03:30:46 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)	Associate Director, Quality Assurance	18 Jan 2024, 12:35:22 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	19 Jan 2024, 05:14:23 PM	Approved