IP Preparation and Administration Instructions for JNJ 68284528

Instructions for Thaw Procedure

Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA for Subjects/Participants with Multiple Myeloma

IPPI Version 10.0 27OCT2021

Slide Deck Version 10.0 30NOV2021

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IPPI v10

This presentation highlights important elements of the Investigational Product Preparation Instructions (IPPI). It is not a replacement for the IPPI, which must be closely followed.

Refer to TV-TEC-133339 for full details.

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IPPI v10

- Sites may utilize site prepared worksheets as an alternative but must complete all the steps in the specified order and document all entries as shown on the worksheet.
- Preparer must be trained on current version of the IPPI and document that this training has been completed.
- The training document needs to be stored in the site trial center file.

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Preparation changes to v10 from v9

IP expiry time expanded
to 150 minutes

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Investigational Product

Storage Conditions:	➢ JNJ-68284528 is supplied as a frozen liquid and should be stored at temperatures ≤ -120 ° C in vapor phase of liquid nitrogen and be protected from light. ➢ IP is considered a **Cell Therapy Product** and should be handled according to current safety guidance's and local site procedures for blood products and GMOs (genetically modified organisms).
Unique elements of IP Preparation:	➢ The IP bag(s) will be either 70-mL or 30-mL infusion bag containing cryofrozen IP. ➢ It is **recommended** IP preparation be performed at the subject/participant's bedside or in close proximity to the subject/participant. ➢ Transportation of the IP should occur from the site-specific storage location to the subject using a liquid nitrogen vapor phase transport container to maintain the temperature at ≤ -120^{0}C. ➢ **The total time to thaw the IP must remain within 15 minutes. Do not leave IP thawing longer than necessary .** ➢ Once thawed, **do not shake, refreeze or refrigerate** IP. ➢ The IP should not be dispensed or administered if there is a concern about the quality of the IP. Refer to the CTPPM for specific details for product quality concerns.

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Ancillary Materials

Details	Quantity
Sealable plastic bag with a tight closure system (For thawing of IP Bag) Sterile bag recommended	1
Water Bath (approximately 5L capacity) or dry thawing device capable of maintaining constant temperature of 37°C ± 2°C or equivalent (as agreed upon by Sponsor)	1
Use appropriate solution as specified by site or manufacturer. Recommended sterile water for irrigation or sterile 0.9% Sodium Chloride, USP/EP/JP	1
Portable Vapor phase nitrogen transport container, previously “charged” to ensure it is and will maintain ≤-120C temperature	1

Expiry Label

Prepare expiry label for the thawed IP.

At minimum, the label should have:

Maintain thawed IP at room/ambient temperature and light conditions.
Avoid direct sunlight exposure. Route: Intravenous

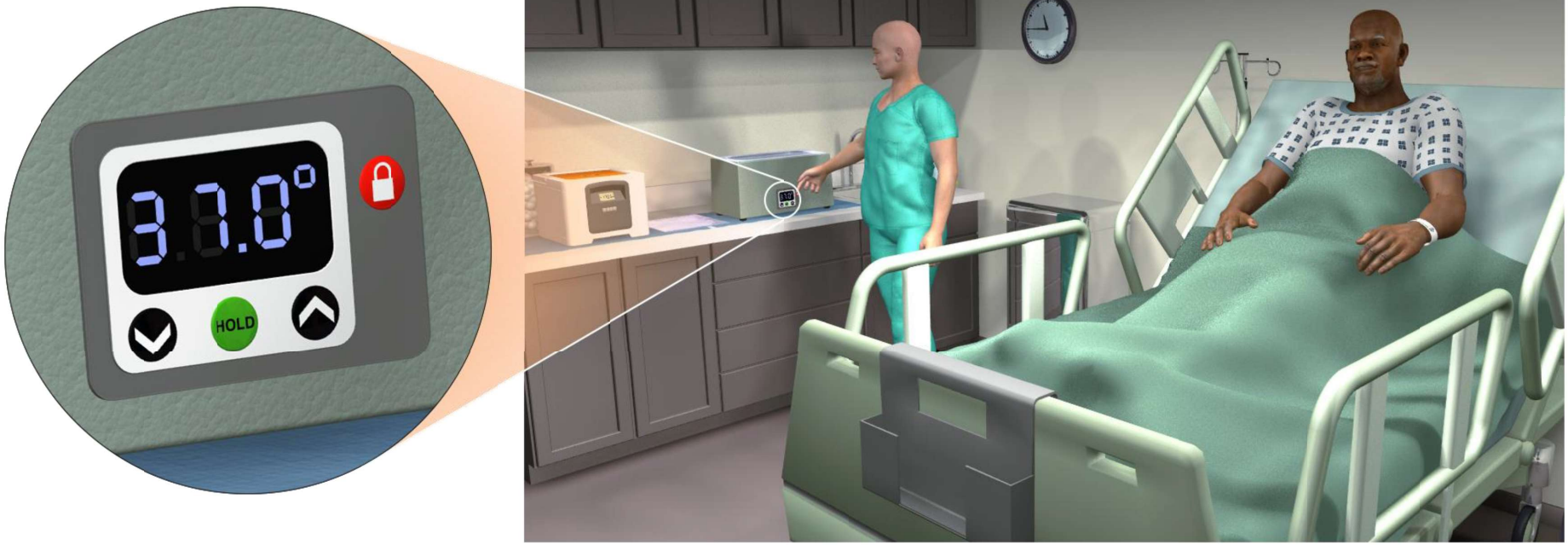
Expiry*: _____/_____/_____ _____:_____
DD MMM YYYY hh mm

**Expiration time is 150 minutes after the IP infusion bag has been thawed.*

Prior to beginning this section, confirm that administration line is in place.

Verify that the DIN, Apheresis ID or SEC/DIS and subject identification on the IP bag matches the subject/participant identification when removing from long term storage unit. Document verification according to current site procedures.

Ensure that the IP Infusion Bag has been delivered to the subject bedside or near the subject administration area using the liquid nitrogen transport container at ≤ -120°C.



Ensure the required thawing device has been cleaned, sanitized and prepared for use according to site procedures.

Adjust the temperature of thawing device to 37°C ±2°C.

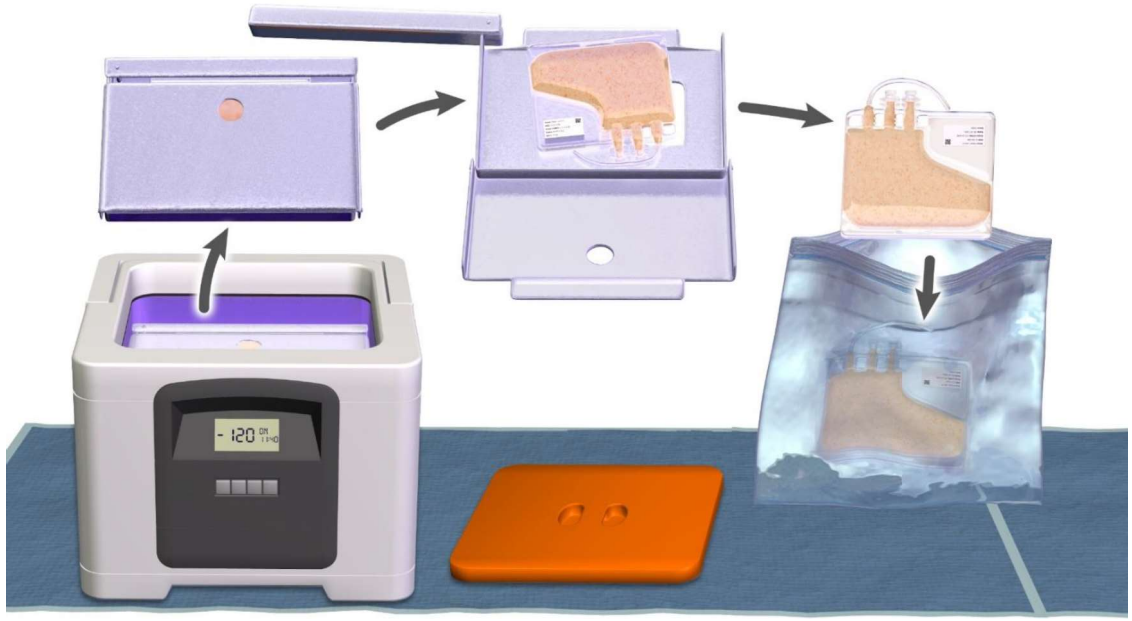
If multiple bags are to be administered, the site should prepare and administer one IP bag at a time.

When temperature of the thawing device has reached 37°C ±2°C remove the IP infusion bag from the portable liquid nitrogen container and verify that DIN/Apheresis ID or SEC/DIS and subject/participant identification on the IP bag match.

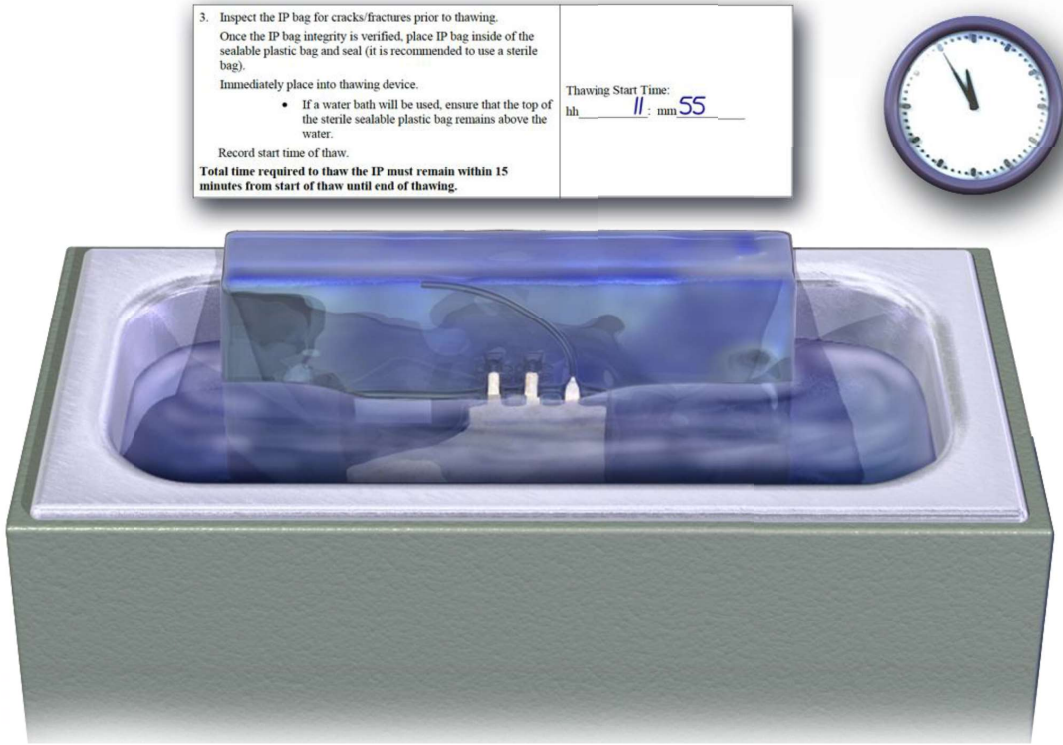
Inspect the IP bag for cracks/fractures prior to thawing.

Once the IP bag integrity is verified, place IP bag inside the recommended sterile sealable plastic bag and seal.

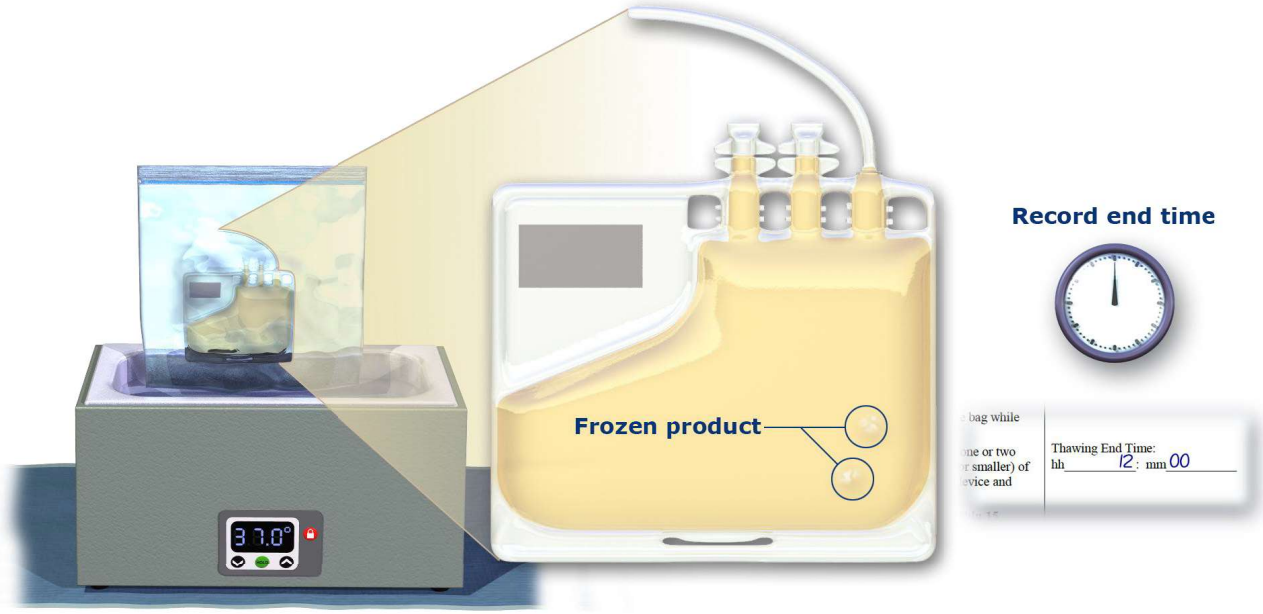
Immediately place into thawing device.



Record start time



If a water bath will be used ensure that the top of the sterile sealable plastic bag remains above the water.



Allow the IP Infusion Bag to thaw in the thawing device. Gently mix the contents of the bag if thawing in the water bath.

Monitor the thawing process and when there are only one or two small clumps (approximately 18 mm in diameter or smaller) of frozen product left remove the bag from the thawing device and record the end of thaw time.

Total time required to thaw the IP must remain within 15 minutes from start of thaw until end of thawing.

Remove the IP bag from the sealable plastic bag and wipe dry.

Gently invert the bag five times to mix.

Inspect the thawed IP infusion bag for presence of cell clumps. If present, use a gentle squeezing motion to disperse the clumps until no visible clumps remain.

Confirm IP is thawed, free of ice crystals and cell clumps.

IP will be administered with or without 170 micron or larger non-leukocyte reducing filter even if small (approximately 18 mm in diameter or smaller) clumps are present.

Document expiration time of thawed IP Infusion Bag as: Thawing End Time + 150 minutes.

Document on the site generated IP post thaw label the expiration date/time and apply the expiry label to the IP Infusion Bag.

Immediately begin the administration procedures.

Repeat entire process for multiple bags of IP, at the request of the administrator.

Hand the thawed IP to the infusion administrator.