IP Preparation and Administration Instructions for JNJ 68284528

Instructions for IP Administration

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.
- Administrator must be trained on the current version of the IPPI with corresponding associated training resources and document that this training has been completed.
- The training document needs to be stored in the site trial center file.

Administration Changes to v10 from v9

Ancillary materials of construction restrictions have been removed.

Administration set restrictions have been removed.

Administration set determined by site practice.

Flushing methods expanded to allow each site to flush per their procedure (0.9% Sodium Chloride must be used).

Expiry time expanded to 150 minutes.

IP may be administered via gravity or IV pump.

Important information about JNJ-68284528

The 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).

Once thawed do not shake, re-freeze or refrigerate.

The IP expires 150 minutes after it has been thawed. IP administration must be completed (including flush) within 150 minutes after thawing.

IP administration is to be performed at room/ambient temperature and light conditions. Avoid exposure of IP to direct sun light.

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Important information about JNJ-68284528

The IP should **not** be dispensed or administered if there is a concern about the quality of the IP.

Do not deviate from the instructions in the IPPI.

Do not pre-filter IP into a different container, wash/re-suspend in alternative media without consulting the sponsor.

Do not use a leukocyte depleting in-line filter.

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Ancillary Materials

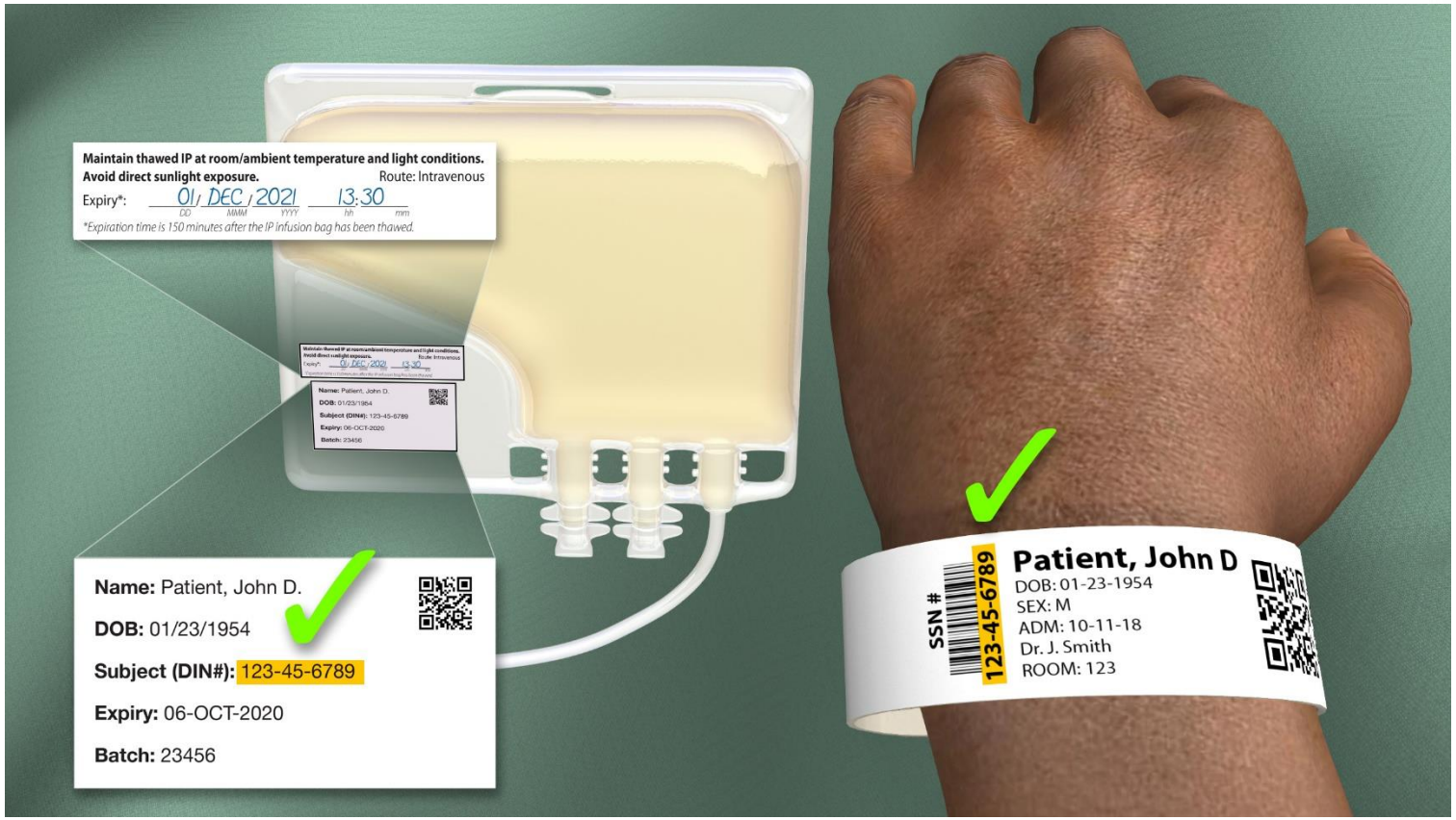
Details	Quantity
IV Administration Set	1
Optional: A 170 µm or larger non-leukocyte binding in-line or add-on filter	

Ancillary Materials

Details	Quantity
Extension set, or site-determined equivalent, with needle-free connector to be used with peripheral IV catheter	1
0.9% Sodium Chloride Injection, USP/EP/JP appropriately sized infusion bag (for priming & post infusion flush)	1-2

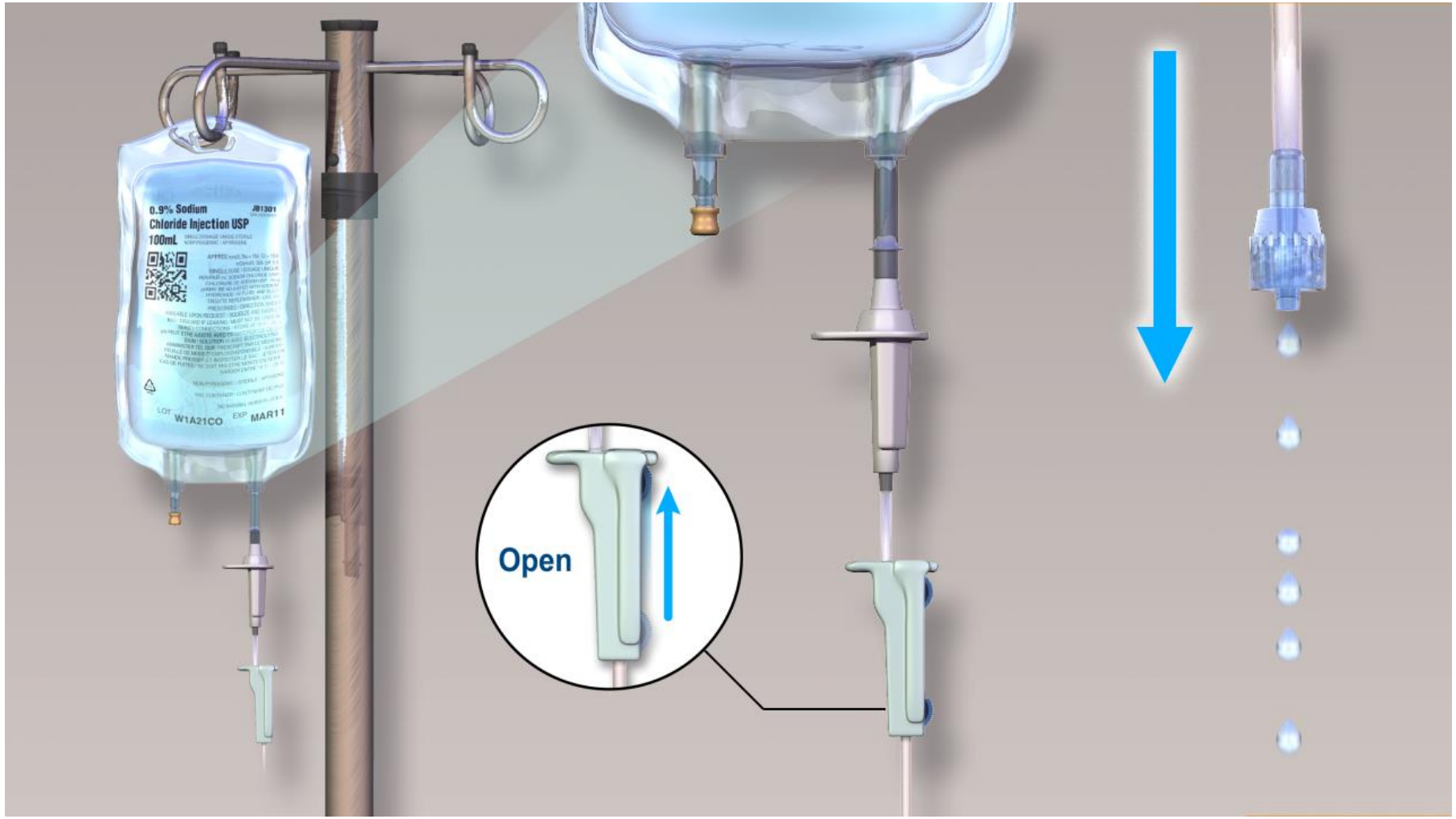
A new admin set, filter, and IV bag must be used for each IP administration.

IP Administration Instructions



Ensure DIN, Apheresis ID or SEC/DIS and subject identification on the thawed IP bag matches subject.

Document verification according to current site procedures.



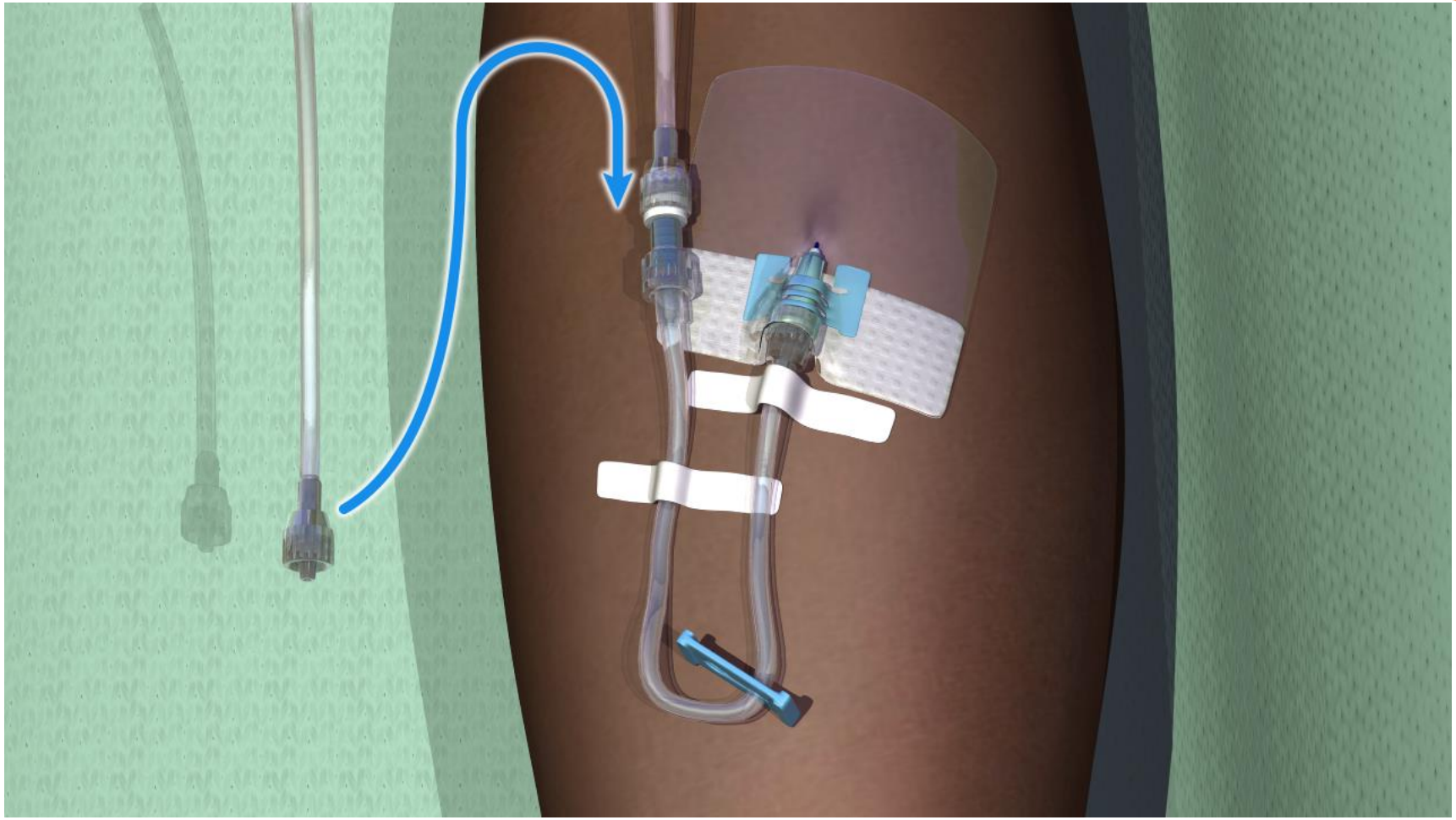
Prime the administration line with 0.9% Sodium Chloride.

A 170 micron or larger non-leukocyte depleting filter in-line or add-on filter is optional.

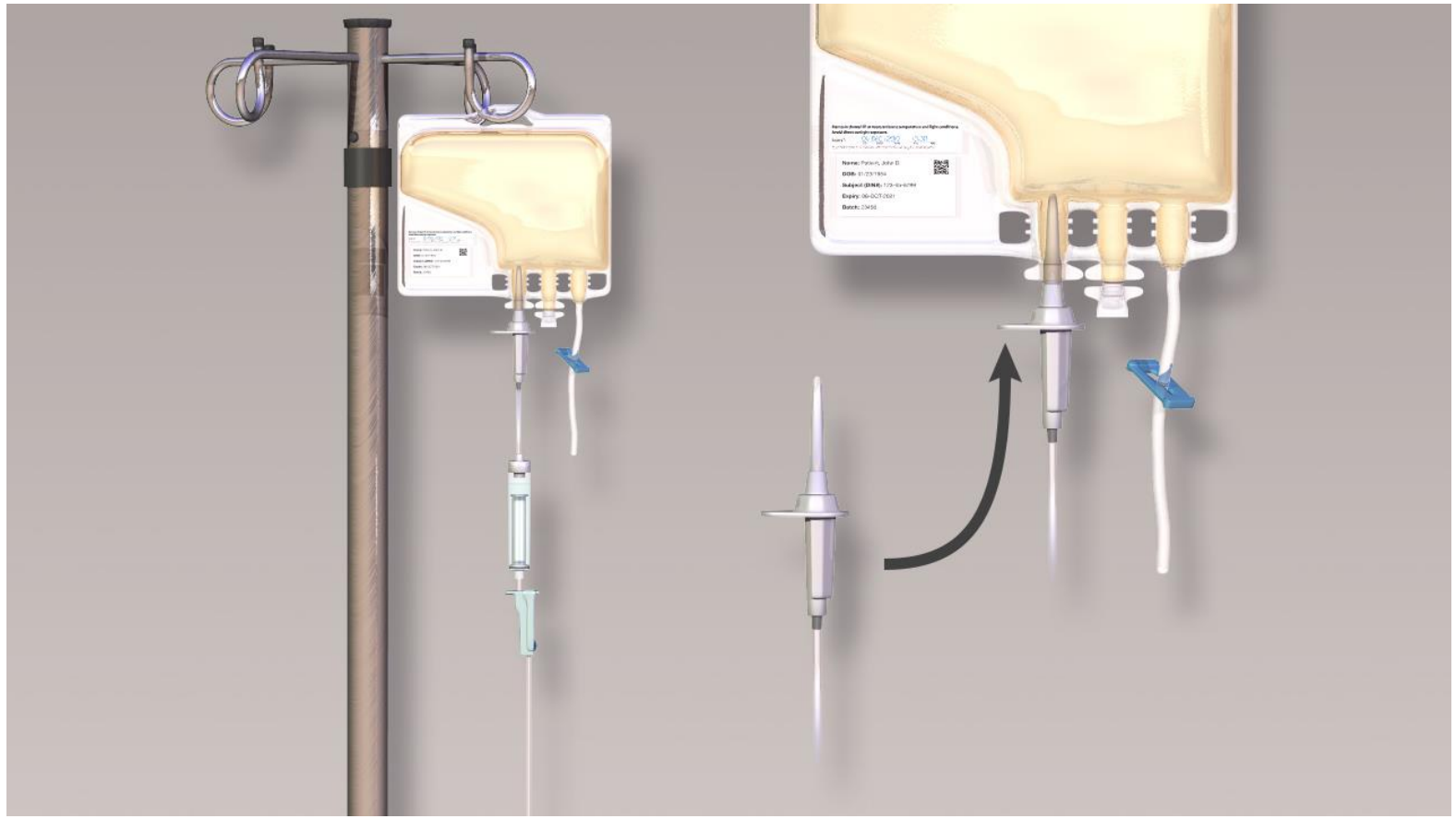
If used, ensure filter is primed with 0.9% Sodium Chloride.

Note: Administer IP with or without the optional filter, even if small (approximately 18 mm in diameter or smaller) clumps are present.

Document filter usage.



Connect the distal end of the primed IV administration set to the IV extension set or IV catheter.



Connect the proximal end of the administration set to the IP bag

Note: If site practice connect the proximal end of the administration line to the IP bag before connecting the distal end to the subject/participant, this is acceptable provided the administrator ensures clamp is closed to prevent IP spillage during connection procedure.

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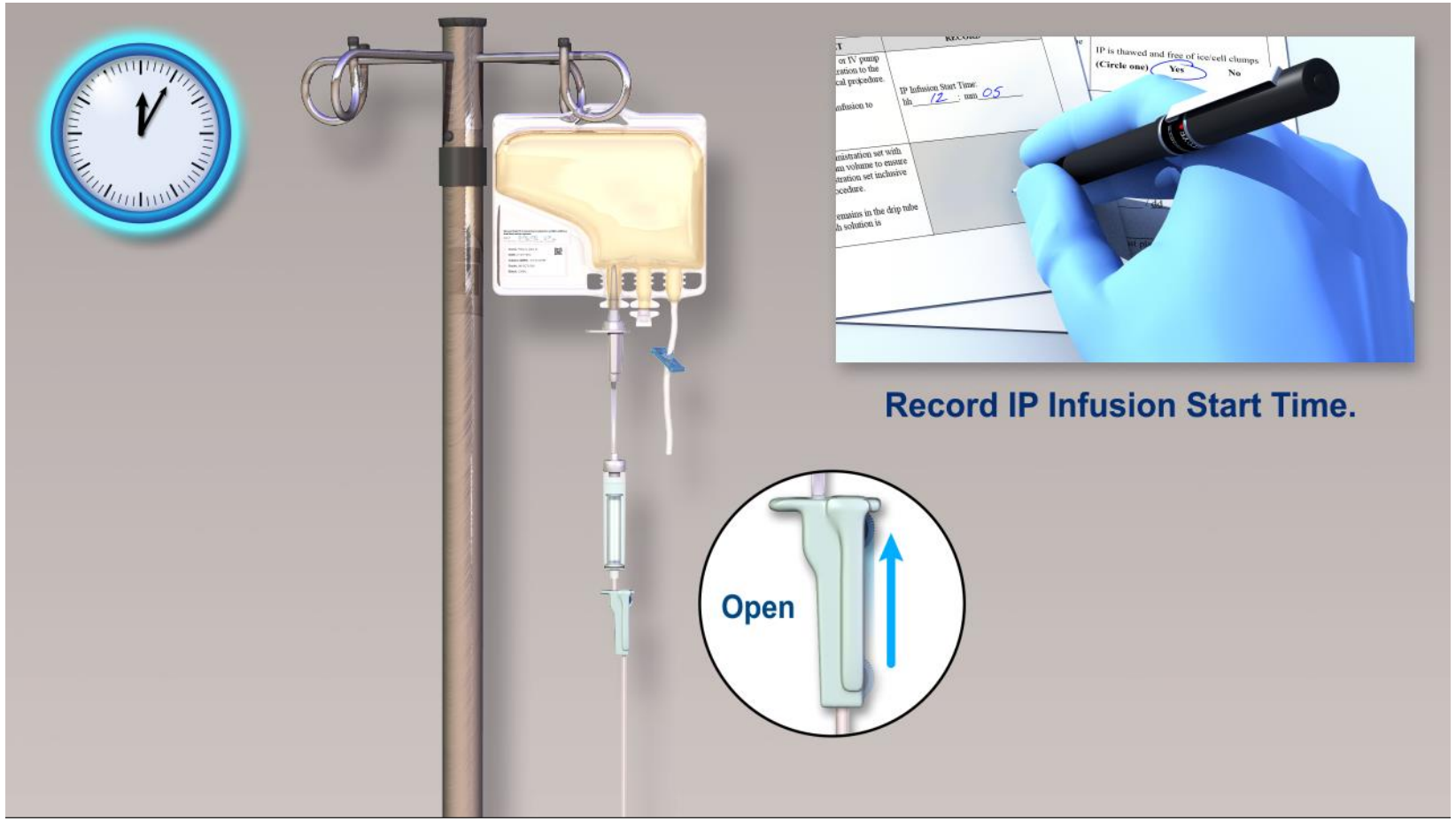
Begin IP infusion by administering via gravity or IV pump at an infusion rate that is suitable for administration to the subject/participant in accordance with site/local procedure.

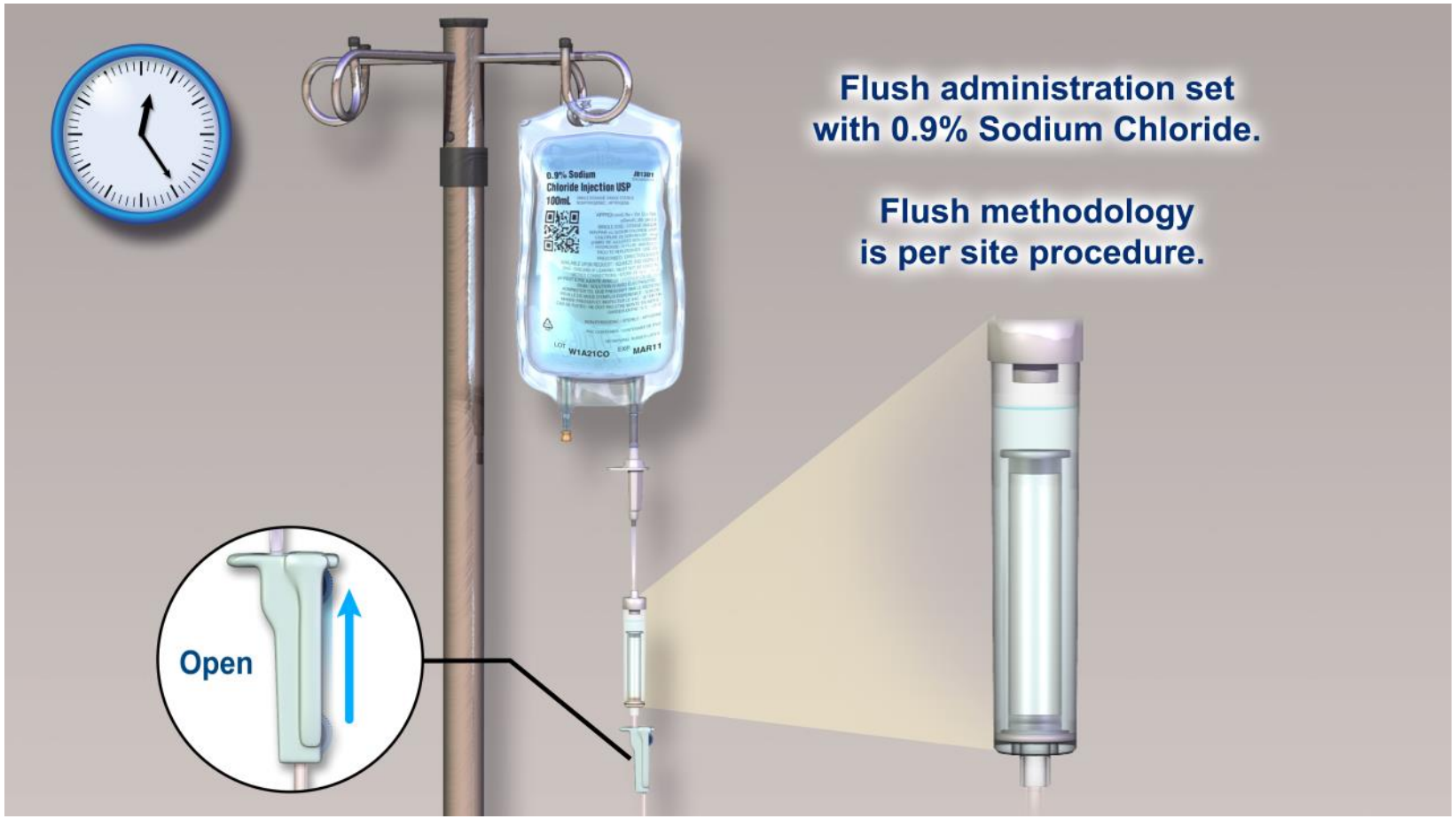
If needed, gently agitate the IP bag during infusion to prevent any cell clumps.

Record IP infusion start time.



When infusion bag is empty, flush administration set with 0.9% Sodium Chloride using a minimum volume to ensure the total length of the primary administration set inclusive of the drip tube is flushed, per site procedure.

Ensure that no IP or flush solution remains in the drip tube or filter if used, and that all IP/Flush solution is administered.



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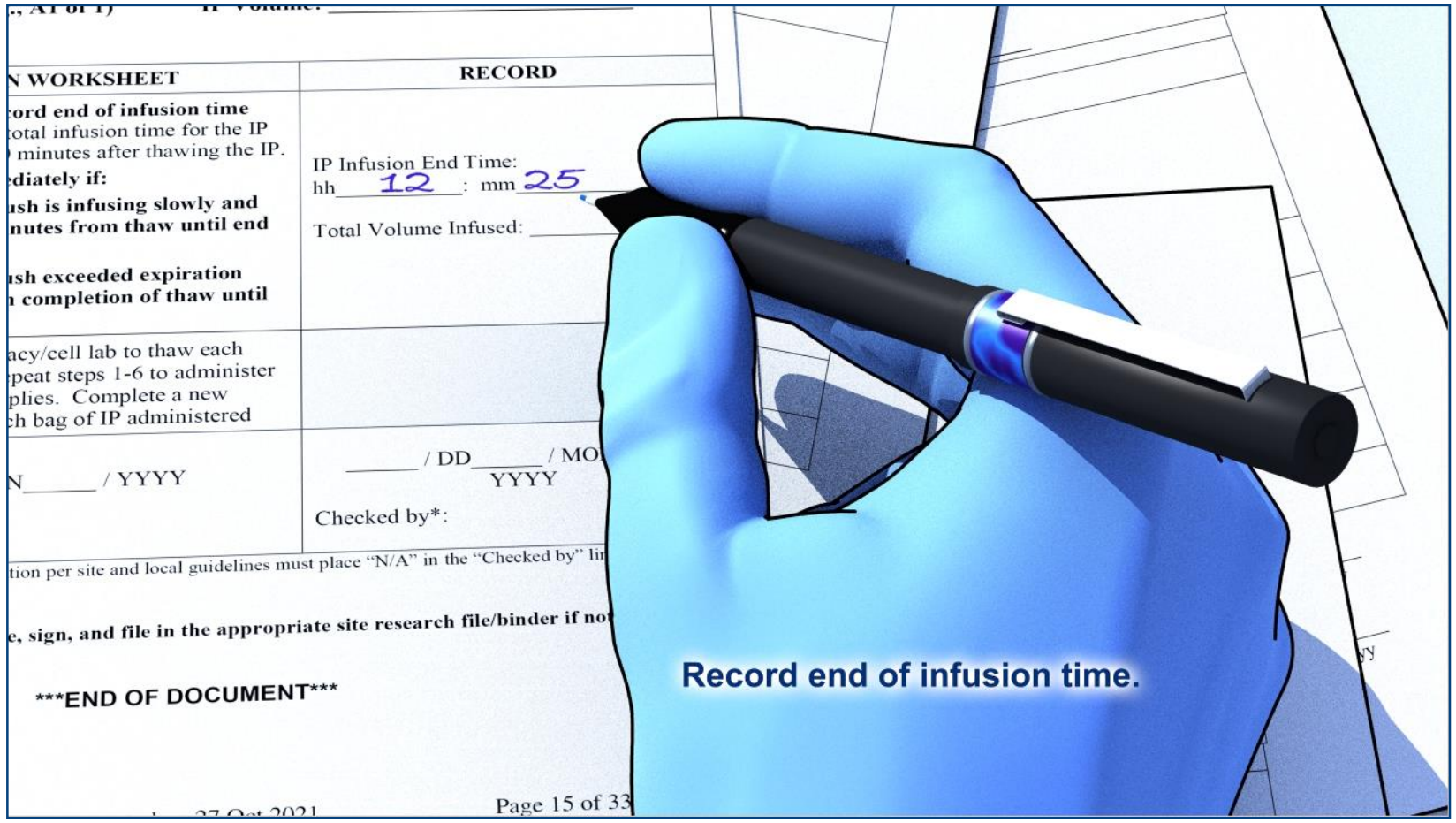
Post completion of the flush, record end of infusion time and total volume infused.

The total infusion time for the IP and the flush must be within 150 minutes after thawing the IP.

All used IV bags and any material remaining in an IV bag after administration should be discarded per local site procedures.



Document in Subject/Participant source document and CRF for both IP bag infusion and post infusion flush:

- ❑ **The IP bag volume**
- ❑ **The start time, stop time(s) and/or end time of the IP infusion, including IP infusion interruptions**
- ❑ **If filter was used**
- ❑ **The volume infused with each IP infusion stop or end time**

Special Considerations

A CVC with an in-line valve is not recommended to be used with a gravity infusion.

Notify Janssen Site Manager immediately if:

- ❑ **The IP infusion and 0.9% Sodium Chloride is infusing slowly and likely to exceed 150 minutes from thaw until end of infusion.**
- ❑ **The IP infusion and 0.9% Sodium Chloride exceeded expiration time (150 minutes from completion of thaw until end of infusion).**
- ❑ **Follow site procedures to ensure continued patency of the catheter with 0.9% Sodium Chloride as the flush solution while notifying the Site Manager.**