

Cryopreserved IMP cells for clinical use - Information and Handling Instructions

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Advanced Therapies Unit:

NHSBT

Tel No

Fax No

Product Information and handling instructions
IT IS ESSENTIAL THAT ALL INSTRUCTIONS ARE READ BEFORE USE

Clinical indications: This product is intended for infusion to a unique patient ID recipient only.

Contraindications, cautions: All labels and trial paperwork should be matched prior to infusion of this product. In the event of damage to the inner bag containing the product, the sterility of the contents will have been compromised.

Adverse incidents/reactions: Any adverse incidents/reactions associated with the administration of this product should be reported immediately on the adverse event report form appropriate to each receiving site and faxed/emailed to MHRA. A copy should be sent to the Advanced Therapies Unit using the address details above.

Storage and handling: Cryopreserved products must be transported in a validated and approved container and appropriate records kept according to local procedures. The product must only be handled by trained NHSBT or hospital staff. The temperature is maintained at < -150°C.

Please note: The product is ultra cold. Handle only with thermally insulated gloves. The bags are brittle and fragile. Handle with care.

Only remove one bag at the time and always store the remaining bags in the dry shipper. Keep the lid on the dryshipper, apart from gaining access for bags, in order to maintain the correct temperature. If applicable, the cryobags are individually packed in a cardboard box for transport purposes. These are labelled with an outer secondary label with named patient, and specific batch details.

Dosage: The dose required for infusion must be requested by a prescribing clinician/trial coordinator and detailed on FRM5660 sent to the Advanced Therapies Unit prior to the required date of issue. Batch details are detailed on this form.

Administration: The product is for NAMED patient use only and the patient should be monitored during infusion in accordance with written local procedures. Refer to local hospital standard operating procedures for further details on administration. If applicable, infusion of DMSO should not exceed 1ml/kg/day.

Disclaimer: The Advanced Therapeutics Unit has taken great care in the processing of the supplied product in order to provide material of the highest quality. However, the NHSBT assumes no responsibility or liability for the clinical use of the product it product. **The decision to use the products rests with the prescribing clinician.**

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Procedure for Thawing Cryopreserved Cells

- This procedure should be carried out by a trained member of staff only.
- Thaw only **if the patient has been prepared for re-infusion**
- A clean, decontaminated, water bath is required. Fill with sterile water for irrigation or, preferably, isotonic saline BP on the day of infusion. Empty the water bath at the end of each infusion session. Clean, dry and decontaminate after use. Records of decontamination should be maintained.

Thawing instructions

Warning
Danger of cold burns. Handle with insulated gloves!

1. Check and record, the water bath temperature; it **must** be between 35°C and 38°C.
2. Check the dryshipper alarm status. Only proceed if in normal status.
3. **Remove only one bag at a time from the dryshipper for thawing.** Do not remove the next bag until ready to infuse. **Check the details on each bag correspond with the accompanying documentation and the intended recipient.**
4. In the event of a discrepancy return the bags to the dryshipper and contact the Advanced Therapies Unit immediately. **Do not proceed with thawing.**
5. Examine the outer wrapping and inner bag, for damage. In the event of any inner bag damage, report to ATU (on the numbers provided) for discussion and decision on the use of the bag.
6. The decision to use the cells rests with the prescribing clinician.
7. If the details are correct and the inner bag is intact, continue with thawing. Use insulated gloves to remove a bag from the vessel and sterile gloves to thaw. Immerse the double wrapped bag into the waterbath. Agitate contents by massaging the bag gently horizontally in the water, releasing frozen clumps around ports. **Do not squeeze, knead or rotate the bag, this may damage cell contents.**
8. Thawing of each bag takes approximately 2-4 minutes. **Do not re-freeze previously thawed products for later use.**
9. Check that the contents of the bag, including the entrance to the ports, are completely thawed and remove the bag from the water bath as the last ice crystal thaws.
10. Dry the outer wrapping. Inspect the bag and contents for damage/leaks.
11. Cut open the wrapping very carefully, avoiding cutting near the "pig-tail".
12. Remove the inner bag carefully.
13. **Infuse the contents immediately.**
14. Monitor the patient according to protocol for any side effects.