



STANDARD OPERATING PROCEDURE FOR COMMERCIAL USERS

The Nomad MD Range of Cold Carriers for Vaccines and other Medical Products are Insulated Passive Cold Carriers designed for use as primary containers for the transport of Vaccines, Blood and Blood Derivatives, and other Medical Products.

1. Scope

This SOP applies only to the MD Range of products with the use of HTIceGel Refrigerant. It describes the safe preparation and use of the products to obtain best cold life performance. It is not a performance guarantee.

The MD Range was designed to be used principally as a standalone temporary containment or storage function where temperature limits are essential in transit, or during use, for vaccines and other medical products, and complies with Medical Directive 93/42EEC (CE Marking).

2. References

Refer to the SOP issued with digital thermometer.

3. Definitions

HTIceGel – Water based Refrigerant gel with a freezing temperature of 0 C.

HTIce Gel Bricks – White MDPE container for HTIceGel.

HTIce Packs - Flexible packs containing HTIceGel.

Temperature limits – Upper and lower temperature advised by the User. For Vaccines normally +2 C to +8 C, or WHO for vaccine boxes " to 10 C from close of lid but not lower than 0 C".

Sensor - the probe attached by cable to the digital thermometer.

Liner – A liquid tight insulated removable liner with pockets to contain the HTIceGel Bricks/Packs.

Room Temperature – Controlled temperature of approximately 18 C in the area for preparation and packing out.

4. Procedure

4.1 Set the refrigerator at -20 C or lower.

4.2 Check that all HTIceGel Bricks/Packs are in a liquid state and do not leak. Reject any leaky packs.

4.3 Place the HTIceGel Bricks/Packs in a single layer flat on trays in the refrigerator, sufficiently spaced for air flow over the surface of the Bricks/Packs.

4.4 Freeze the HTIceGel Bricks/Packs for 24 hours minimum. The bricks must be completely solid before use.

4.5 Open the lid of the MD Cooler and put the liner in place.

4.6 If a digital thermometer and /or high temperature alarm is installed, check the batteries, and replace if necessary. Clean and check the cable and sensor.

- 4.7 Remove the HTIceGel Bricks/Packs from the freezer, and condition by placing them flat in a well ventilated position at room temperature until the surface temperature rises to above 0 degrees (dew will form on the surface of the bricks at this point).
- 4.8 Place the HTIceGel Bricks/Packs in the liner pockets.
- 4.9 Close the lid, and wait for the temperature inside the box to reduce to below 8 C.
- 4.10 Open the lid and transfer the Vaccine or other product directly from the refrigerator to the MD Medical Cooler.
- 4.11 Place the thermometer sensor at the centroid of the cold space.
- 4.12 Check that the closing surfaces are clean and free of loose objects. Wipe the seal surfaces carefully. Close the lid and engage the over center catches.
- 4.13 Check that the digital thermometer and /or high temperature alarm are operating correctly.

5. Care and Maintenance

- 5.1 Clean the cold space the liner after each use using detergent and warm water. Do not Use abrasives on the inner box and lid surfaces. Rinse off with clean water. Disinfect by wiping out with a solution of 5.25% sodium hypochlorite.
- 5.2 Clean each HTIceGel Brick /Packs after each use by washing in detergent and warm water. Disinfect by wiping the surface with a solution of 5.25% sodium hypochlorite.
- 5.3 Inspect each Brick/Pack for damage or leaks.
- 5.4 Clean the external box and lid surfaces with warm water and detergent. Do not use abrasives. Rinse off with clean water.
- 5.5 Protect the HTIceGel Bricks/Packs from impact and sharp objects. Handle carefully and DO NOT DROP OR EXPOSE TO HEAT OR DIRECT SUNLIGHT.

6. Occupational Safety and Health

- 6.1 HTIceGel is Non-toxic and Non-Hazardous but DO NOT EAT.
- 6.2 Gloves are recommended for handling HTIceGel Bricks/Packs out of a freezer.
- 6.3 If an accidental release occurs, scoop up and place in a suitable container. Flush the area with plenty of water. Be aware that HTIceGel is very slippery.
- 6.4 Eyes: Separate the lids, and flush with plenty of water.
Ingestion: Give plenty of fresh water and seek medical aid.

7. Statement of Liability

Liability arising directly or indirectly from incorrect or negligent preparation or use of these products is for the User.

Unless otherwise required by law, in relation to claims of loss or damage arising out of or from the operational use of the products herein, the Manufacturer shall not be liable for direct, consequential, special, incidental or indirect damages no matter what the circumstances, nor when or how so arising.

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