thermoscientific

Instructions for Use for Nalgene™ General Long-Term Storage Cryogenic Tubes

REF **5005-0015**

Intended Use

These polypropylene containers are covered specimen receptacles and are intended to be used for the collection, and preservation and/or transport, of any type of tissue specimen (e.g., biopsy tissue) collected from any body part for in vitro diagnostic investigation. They do not contain patient-contact specimen sampling/extraction devices such as swabs/brushes. The container can be used to store samples down to the vapor phase of liquid nitrogen temperatures. The containers are disposable and for single use only. Intended for laboratory and healthcare professional use.

General Instructions for Use

1. Fill the containers to no more than 90% total capacity.
2. Ensure that the threads of container and cap are dry before closing.
3. Tighten the cap.
4. Specific instructions for use of these containers in cold storage must be defined and implemented by the end user according to the type of sample stored as well as the downstream application.
5. If used with liquid nitrogen (LN_2), only place these cryogenic containers in the vapor phase of the LN_2.

Product Warehousing Temperature

Room temperature (20°C to 26°C or 68°F to 77°F)

Quality Control Specification

5005-0015

Parameter	Specification
Pyrogen (endotoxin)	< 0.5 EU/mL
Irradiation Certificate of Processing Review	19.0 - 28.0 kGy

Precautions and Warnings

1. Warning: For use in vapor phase of LN_2 only. Submersion can lead to hazardous situation.
2. Overfilling can lead to caps bursting during sample expansion, which can lead to leakage and contamination.
3. For single use only.
4. Do not use after expiry date.
5. Do not use the product if the product packaging is unsealed or damaged.
6. Fluid path is sterile and non-pyrogenic while cap is intact. Discard any tube that arrives with cap missing or askew.
7. If samples are being shipped by methods other than ground, shipping on dry ice to prevent leakage is recommended.
8. Dispose of used tubes in appropriate biohazard collection container.
9. Report any serious incident that occurred in relation to these devices to the manufacturer and EU competent authority.

Report to the manufacturer and local competent authority if you experience unexpected operation or serious incident with the device during or because of its use. The manufacturer will support and if relevant report it to the competent authorities.

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Made in USA

EC REP

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Symbols Glossary in accordance with ISO 15223-1:2016 and other standards

Symbol	Title of Symbol	Description of Symbol	Reference Number
	Manufacturer	Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
EC REP	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
	Non-pyrogenic	Indicates a medical device with a non-pyrogenic fluid path.	5.6.3
UDI	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.	5.7.10
CE	European Conformity Mark	Indicates European technical conformity.	98/79/EC