

# *GT cryogenic containers*

Maintenance manual



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This manual complies with Directive 93/42/EC concerning medical devices.

The GT device is only intended for cryobiology. For any questions regarding how the device works, please contact:



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## 1. General information

This manual is only intended for staff who are trained and approved in maintaining the GT device. Before handling the GT device, read this manual and the following safety instructions carefully.

### 1.1. Delivery checks

Upon receipt of the GT device, conduct the following checks:

- Packaging not damaged
- No sign of impact, breakages, etc.
- The device, manual and level indicator (optional) present in the packaging

### 1.2. Precautions in the event of faults

Full safety cannot be guaranteed in the following cases:

- The container is visibly damaged.
- After prolonged storage in unsuitable conditions.
- After severe damage sustained during transit.
- Loss of the container's thermal performance (see appendix in the document on monitoring performance)

If you suspect that the container is no longer safe (for example as a result of damage sustained during transit or during use), it should be withdrawn from service. Make sure that the withdrawn equipment cannot be accidentally used by others. The apparatus should be handed over to authorised technicians for inspection.

### 1.3. General instructions

You are only authorised to handle the equipment mentioned in this document if you have read through this entire manual and all safety instructions and have been trained and certified in maintaining this device.

To ensure the safe and correct use of the device during service and maintenance, it is essential that all personnel observe standard safety procedures.

In the event the cryogenic equipment does not seem to function correctly under normal usage conditions, only someone who has been fully trained by the manufacturer is allowed to work on the cryogenic device and its peripheral components. Users must not take action themselves due

to the health and/or safety risks. In order to avoid the loss of too much cold, the time until the maintenance technician performs servicing must be as short as possible.





If samples get stuck inside the device, add nitrogen to keep the samples cold, which will make it possible to extend the time allotted for authorised personnel to start servicing.

The installation of remote monitoring options or devices will improve the safety of the cryogenic system. Regular inspections must also take place.

The device's service life can only be maintained if all of the recommendations made in this manual are followed.

#### 1.4. General precautions for use

Wear personal protective equipment (PPE) when handling the device:

Symbol	Meaning
	Protective cryogenic gloves are compulsory
	Fire-resistant protective overalls (long sleeves) are recommended
	Protective goggles are compulsory
	Foot protection is recommended
/	Oxygen meter

#### *Protection*

The general precautions for use are the same for all cryogenic tanks:



### **Cold burns and/or frostbite**

- On the neck and cap, after opening or while filling.
- By liquid nitrogen splash when opening or removing fittings.
- On the lock, during or immediately after filling
- On the neck and the lid after opening
- Liquid nitrogen may spill out of the device when handling canisters or racks. Wear personal protective equipment in accordance with the safety instructions.



### **Trapping**

- By the cap when closing the device.

### **Crushed feet**

- By the casters, and the cryogenic device when handling.



You must never touch objects that have been in contact with liquid nitrogen with your bare hands.



It is essential to protect your hands and face with appropriate individual protective equipment. Every time the device is used.

Always wear special gloves and goggles when handling liquid nitrogen.



Liquid nitrogen is at a very low temperature (-196°C).



Regular checks of the evaporation rate provide assurances that the product has retained its original characteristics.

Check there is no frost on the neck or outer casing of the device on a daily basis. If there is, stop using the cryogenic device and immediately contact your distributor responsible for maintenance.

Check the condition of the cap (deterioration of the polystyrene, uncoupling of the cover). If there is substantial wear and tear, replace the cap to help maintain the device's performance.



If liquid nitrogen drips onto the pump check valve, it may expand and no longer be leaktight.

It is recommended to use the device on a flat, even surface to ensure it remains stable.



Liquid nitrogen used in storage chambers evaporates into the air; 1 litre of liquid nitrogen releases around 700 litres of gaseous nitrogen. Nitrogen is an inert, non-toxic gas, but displaces oxygen when released into the atmosphere. Once the atmospheric oxygen content falls below 19% the human body is at risk.

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All rooms and areas that house storage tanks containing liquid nitrogen should be well ventilated at all times and equipped with at least one oxygen gauge. All personnel should be informed of the risks associated with the use of nitrogen.

Refer to current guidelines and contact your distributor.

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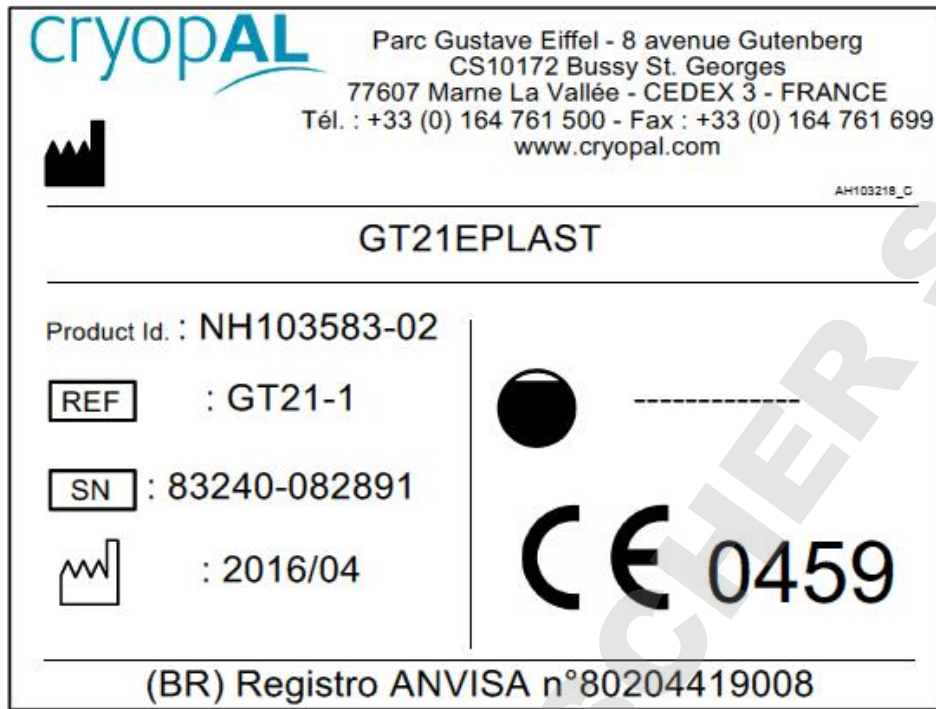
The device must be filled with cryogenic liquid nitrogen in a well-ventilated area (outside) or in a room equipped with a constant ventilation system adapted to the size of the room. The room must also be equipped with an oxygen monitoring system with a display located outside the room, and the user must be equipped with a portable oxygen monitoring system.

The necessary safety conditions and the provision of safety systems for operating a cryogenic room are the responsibility of the operator.

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### 1.5. Description of labels





Labels found on the GT device

### 1.6. Description of symbols

	Manufacturer		Important: Low temperature
	Refer to the instruction manual		Gloves must be worn
	Goggles must be worn		Ventilate the room
	Do not touch frosted parts		Product reference code
	CE marking, complies with Directive 93/42/EC		Serial number
	Date of manufacture		Capacity in litres



## 2. GT device

### 2.1. Device overview

This manual specifically concerns the cryogenic devices in the *GT 2, 3, 9, 11, 14, 21, 26, 35, 38* and *40* product ranges, which are unpressurised devices designed for use in medical laboratory environments and for storing biological specimens that have been previously frozen. This manual will discuss their components and their usage.

The devices in the *GT* product range are unpressurised cryogenic tanks used to store and preserve biological specimens that have been previously frozen in liquid nitrogen at  $-196^{\circ}\text{C}$  (liquid nitrogen is a cryogenic fluid).

There are two ranges of *GT* tank:

- The long holding time *GT* range (neck diameter  $\leq 50$  mm to minimise nitrogen loss through evaporation)
- The large capacity *GT* range (neck diameter  $\geq 80$  mm so more canisters can be used)



*GT tanks*

The devices are equipped with caps designed with a concentric hole, intended for use with a temperature probe such as the T° Tracker. If no probe is used, the hole is plugged using the push rivet supplied with the cap, in order to maintain the device's performance.

Option to close with a standard padlock, except *GT2*.

Light alloy construction, for reduced weight and longer holding time.



The devices must only be used for storing products in liquid nitrogen, and not for freezing. Any other gas is prohibited.

## 2.2. Technical specifications

Manufacturers - Series	Cryopal - GT long holding time series					
Name	GT2	GT3	GT9	GT11	GT21	GT35
Purpose	Storing and preserving vials, straws, bags containing blood/living cells					
Contraindication	Do not use outside of the temperature/humidity ranges stated in the notice					
	Do not fill the tank with anything other than liquid nitrogen					
Performance	Maintains a cryogenic temperature to preserve biological samples					
Operational lifetime	10 years					
Material held	Liquid nitrogen					
Tank material	Aluminium alloy, epoxy fibreglass composite (neck)					
Total capacity (L) <sup>1</sup>	2	3.7	9.3	12.2	21.5	33,6
Diameter of neck (mm)	30	50	50	50	50	50
Weight when empty (kg)	1.9	4.5	8.2	9	13	15
Weight when full (kg) <sup>2</sup>	3.5	7.5	15.7	19	30.4	43
Evaporation (in L/day of liquid) <sup>3</sup>	0.08	0.11	0.11	0.09	0.09	0,09
Warning evaporation (L/day)	0.24	0.33	0.33	0.27	0.27	0,27
Holding time (days) <sup>4</sup>	25	33	84	130	225	350
Materials in direct or indirect contact with the user	Aluminium alloy, epoxy fibreglass composite, polycarbonate, Klegecell (PVC), stainless steel.					

<b>Tanks</b>	<b>Cryopal - Large capacity series</b>			
<b>Name</b>	<b>GT14</b>	<b>GT26</b>	<b>GT38</b>	<b>GT40</b>
<b>Purpose</b>	Storing and preserving vials, straws, bags containing blood/living cells			
<b>Contraindication</b>	Do not use outside of the temperature/humidity ranges stated in the notice			
	Do not fill the tank with anything other than liquid nitrogen			
<b>Performance</b>	Maintains a cryogenic temperature to preserve biological samples			
<b>Operational lifetime</b>	10 years			
<b>Material held</b>	Liquid nitrogen			
<b>Tank material</b>	Aluminium alloy + epoxy fibreglass composite (neck)			
<b>Total capacity (L)<sup>1</sup></b>	13.5	26.7	37	40
<b>Diameter of neck (mm)</b>	80	80	80	120
<b>Weight when empty (kg)</b>	9.5	14.8	19	24
<b>Weight when full (kg)<sup>2</sup></b>	20.4	36	49	57
<b>Evaporation (in L/day of liquid)<sup>3</sup></b>	0.24	0.29	0.18	0.29
<b>Warning evaporation (L/day)</b>	0.72	0.87	0.54	0.87
<b>Holding time (days)<sup>4</sup></b>	56	90	205	135
<b>Materials in direct or indirect contact with the user</b>	Aluminium alloy, epoxy fibreglass composite, polycarbonate, Klegecell (PVC), stainless steel, and expanded polystyrene for the GT40 cap.			

### 2.3. Overview of the product range

References	Product description
GT2-1	GT2 with 3 plastic canisters
GT3-1	GT3 with 6 canisters and 1 plastic level
GT9-1	GT9 with 6 canisters and 1 plastic level
GT11-1	GT11 with 6 canisters and 1 plastic level
GT11-4	GT11 with 6 canisters and 2 plastic levels
GT21-1	GT21 with 6 canisters and 1 plastic level
GT21-4	GT21 with 6 canisters and 2 plastic levels
GT35-1	GT35 with 6 canisters and 1 plastic level
GT35-4	GT35 with 6 canisters and 2 plastic levels
GT3-2	GT3 with 6 canisters and 1 stainless steel level
GT9-2	GT9 with 6 canisters and 1 stainless steel level
GT11-2	GT11 with 6 canisters and 1 stainless steel level
GT11-3	GT11 with 6 canisters and 2 stainless steel levels
GT21-2	GT21 with 6 canisters and 1 stainless steel level
GT21-3	GT21 with 6 canisters and 2 stainless steel levels
GT35-2	GT35 with 6 canisters and 1 stainless steel level
GT35-3	GT35 with 6 canisters and 2 stainless steel levels
GT14-1	GT14 with 6 canisters and 1 stainless steel level
GT26-1	GT26 with 9 canisters and 1 stainless steel level
GT38-1	GT38 with 6 canisters and 2 stainless steel levels
GT40-1	GT40 with 10 canisters and 2 stainless steel levels
GT21-S	Serialized GT21 with 2 stainless steel levels

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## 3. Help

### 3.1. What to do if you are splashed by refrigerated liquid nitrogen

When handling nitrogen to fill the device, there is a possibility it may splash into your eyes and/or on your skin:

#### In the eyes

- Wash the eyes with plenty of water for at least 15 minutes;
- Follow the first aid procedures in place in your workplace;
- See a doctor.

#### On the skin

- Do not rub;
- Remove (if possible) or loosen your clothing;
- Defrost the affected areas by gently and gradually warming them up;
- Do not apply anything to the burnt area;
- Follow the first aid procedures in place in your workplace;
- See a doctor.


*This list is not exhaustive.*

### 3.2. What to do in the event of an accident

- Cordon off the perimeter to prevent any further accidents;
- Act quickly: the first aider must be equipped with personal protective equipment (stand-alone respiratory protection equipment);
- Carry out an emergency evacuation of the victim(s);
- Follow the first aid procedures in place in your workplace;
- Ventilate the area;
- Resolve the cause of the accident.

*This list is not exhaustive.*

### 3.3. Stuck cap

Cause	Solution
Cap frozen onto the neck of the device	Pull hard until the cap comes unstuck. If thoroughly stuck, attempt to defrost the cap slightly using a heat source such as a hair dryer (maximum 60°C). The cover can be removed for easier access to the frozen areas. Then continue to defrost the container completely.
 All ice and/or water must be recovered so that it does not fall into the device.	

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## 4. Storage and handling conditions

### 4.1. Storage conditions

- The premises in which the equipment is stored must be equipped with personal protective equipment (PPE).
- There must be minimum safety distance of 0.5 m around the device.
- Do not store the equipment near heat sources.
- Temperature and humidity ranges during storage (in the device's original packaging):
  - Ambient temperature: -30°C to 60°C
  - Relative humidity: 0% to 85% without condensation
  - Atmospheric pressure: 500 hPa to 1150 hPa
- Ensure that there is sufficient ventilation in areas where liquid nitrogen is stored or used, because liquid nitrogen evaporates and produces large quantities of nitrogen gas, which can reduce the amount of oxygen in the surrounding air in confined spaces and lead to a risk of anoxia. A reduction in atmospheric oxygen levels is unnoticeable when breathing in, so anoxia results in a loss of consciousness then death without any warning signs.
- An oxygen meter, linked to a powerful audio and visual indicator, must be installed near anywhere that liquid nitrogen is stored or handled.
- The device must not be stored in a small, enclosed space (such as a cabinet or closet).
- The devices must be kept upright at all times.

### 4.2. Handling conditions

- Temperature and humidity ranges during operation:
  - Ambient temperature: 20°C ±5°C, away from direct sunlight
  - Relative humidity: 30% to 65% without condensation
- Avoid impact and sudden movements.
- Samples (tubes, bags, cases, etc.) must be protected before being placed in the device.

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## 5. Moving the device

The device may be handled by forklift, in accordance with trade practices, only when it is within its packaging.

Never use a forklift truck to handle the device when it is not in its packaging, always move it by:

- Carrying it by its handles or straps
- Rolling it on its roller base.

This movement is only possible and safe over very short distances (tens of centimetres) in order to access the rear of the device during maintenance.

If the cryogenic container has already been used and must be moved to another location, it must be transported empty and in its original packing, complying with the requirements set by current national and international regulations.



It is forbidden to move a cryogenic device when it is full of liquid nitrogen and contains samples.

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Cryogenic devices are not approved for storage in outdoor environments.

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Special care must be taken to protect the valve from mechanical shocks when moving the device.

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## 6. Installing the GT device

### 6.1. Preparing the room

The device operator is responsible for ensuring that the room complies with regulations, current safety standards, and the following recommendations.

The room where the device will be installed must:

- Allow users to operate the device safely;
- Allow the containers to be inspected, cleaned and maintained from all sides (at least 0.5 m around the equipment);
- Allow the device to be filled in complete safety and security;
- Be equipped with an appropriate continuous ventilation system;
- Be big enough for full and proper usage of the device(s);
- Have a flat, non-porous floor capable of supporting the maximum weight of the device and suitable for refrigerated gases in liquid state;
- Display signs informing of the hazardous nature of refrigerated liquid nitrogen;
- Display user and maintenance notices and emergency procedures;
- Prohibit access to unauthorised persons and have automatic closing door equipped with panic bars;
- Be made from fire-resistant or non-combustible material, in accordance with a 30 min fire resistance classification;
- Be separated, either by sealing or by not having any openings, from rooms used by the public;
- Continuously measure oxygen levels.



**A room equipped with cryogenic devices but without safety features cannot operate in complete safety.**

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**The room should not be used for any other purposes than those defined by your integrator.**

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### 6.2. Installing the device

Validate the following installation steps before starting your device:

Action	OK	NOK
Check the general condition of the device	<input type="checkbox"/>	<input type="checkbox"/>
The staff turning the device on are trained and authorised	<input type="checkbox"/>	<input type="checkbox"/>
Does the room satisfy the safety regulations and standards in force?	<input type="checkbox"/>	<input type="checkbox"/>
Are the dimensions of the room (in particular the clear ceiling height for opening the cap) suitable for installing the medical device?	<input type="checkbox"/>	<input type="checkbox"/>
Is access to the room limited to authorised persons only?	<input type="checkbox"/>	<input type="checkbox"/>
Are the safety instructions and risks related to liquid nitrogen on display?	<input type="checkbox"/>	<input type="checkbox"/>
Are instructions available/accessible near the device?	<input type="checkbox"/>	<input type="checkbox"/>
Is personal protective equipment available/accessible in the room?	<input type="checkbox"/>	<input type="checkbox"/>
Is the floor's load capacity sufficient for the weight of the device?	<input type="checkbox"/>	<input type="checkbox"/>
Is the room equipped with a continuous ventilation system suitable for the size of the room?	<input type="checkbox"/>	<input type="checkbox"/>
Is the room equipped with an oxygen monitoring system (displayed outside the room)?	<input type="checkbox"/>	<input type="checkbox"/>
Are safety distances observed (at least 0.5 m around the equipment)?	<input type="checkbox"/>	<input type="checkbox"/>
Has the medical device been blown through (to eliminate all traces of moisture)?	<input type="checkbox"/>	<input type="checkbox"/>
Are fittings on the device in position (if applicable)?	<input type="checkbox"/>	<input type="checkbox"/>
Is there enough nitrogen available?	<input type="checkbox"/>	<input type="checkbox"/>

### 6.3. Filling an empty tank

#### *Filling*

Filling must only take place with empty tanks, and samples only inserted after the device has been loaded with liquid nitrogen and left to stabilise for 48 hours.

The medical device is filled by directly pouring liquid nitrogen through the neck (take care not to damage the neck while filling and use suitable equipment) using the flexible transfer hose

(suitable for cryogenic applications and compliant with the EN12434 standard) connected to either a storage tank (e.g. a TP) or a transfer line and withdrawal rod.

Pour in the liquid very slowly at first to prevent the liquid from being splashed outside by a strong current of nitrogen gas resulting from cooling of the inner container. Fill your device to  $\frac{3}{4}$  and allow to cool for a few minutes, then fill it up to the top.

Do not allow liquid nitrogen to overflow onto the top part of the tank during filling. If this occurs, check that all traces of frost have disappeared from the neck after 24 hours and monitor the container's performance.

Note: if you are using a medical device that is warm at first, insulation will not be fully efficient until after 48 hours. Liquid nitrogen losses will be high in the first hours and will generally be above the specifications for the first two days. If you are looking for maximum holding time, it is a good idea to top up the liquid nitrogen two or three days after filling.

#### *Check*

To check the remaining liquid nitrogen level, remove the cap and insert the plastic level indicator all the way down to the bottom (be careful of any internal protrusions caused by the canister distributor), leave it for 3 or 4 seconds, take it out and shake it in the ambient air. The level of condensation of moisture in the air will indicate the level of liquid remaining in your device. The accuracy of this measurement is within 2 cm.



## 7. Upkeep and maintenance of the GT device

Upkeep and maintenance of the device must be carried out by trained and authorised personnel.

### 7.1. Equipment required

The tools used for maintenance operations must be non-abrasive and should have no sharp edges or points that could damage the surfaces.

### 7.2. Upkeep/maintenance operations

Operation	Frequency
<b>Defrosting the cap and the neck</b>  Lift and remove the cap from the neck, and use a protective cover on the neck to prevent hot air and moisture entering the cryogenic container. Let the cap ice melt in free air. Wipe carefully before replacing the cap on the neck.  All ice and/or water must be recovered so that it does not fall into the device.	Every 2 weeks
<b>Cleaning the outside of the device</b>   Clean the outside of the device only. The use of acetone, solvents or any other highly flammable or liquid chlorine-based product is prohibited.  Wipe <u>plastic parts</u> with a dry cloth and if necessary with a slightly damp non-abrasive sponge (do not use abrasive powder), or with impregnated wipes.  Ordinary domestic cleaning products (slightly abrasive creams containing ammonia) applied with a sponge will be acceptable for <u>stainless steel parts</u> . Afterwards, rinse with a damp cloth, then wipe and leave to dry.	Every 5 weeks
<b>Cleaning the inside and disinfecting the container</b>  Internal cleaning and disinfection of the cryogenic container are possible if deemed necessary; this is the operator's responsibility. It is essential to use a company authorised for this type of work.	At least once every 5 years and whenever required by the operator
 A disinfecting detergent solution/foam with 3 mg/g	

Operation	Frequency
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didecyldimethylammonium chloride is recommended.

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**Emptying**

Samples must be removed beforehand by the device operator. If emptying the device completely, a transfer pump is recommended.

Thoroughly dry the inside of the cryogenic tank by blowing with dry, de-oiled air, especially the filling pipes and level gauge and safety filling wells.

At least once every 5 years and whenever required by the operator

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**Withdrawal from service**

If the device is taken out of service, thoroughly dry the inside of the cryogenic tank by blowing with dry, de-oiled air to prevent the risk of corrosion.

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8. (\*) *The frequencies shown are for guidance only and should be adjusted by the operator depending on how frequently the device is used.*

Like every other device, your equipment may be subject to a mechanical failure. The manufacturer cannot be held responsible for any type of stored products lost as a result of this failure, even during the warranty period.

Only spare parts made by Cryopal may be used for maintenance. The use of non-Cryopal spare parts may affect the safety of this medical device, and releases Cryopal from all liability in the event of an incident.

## 9. Spare parts



Cryopal assumes no responsibility if:

- A modification has been made to the device and/or its related equipment
- Other accessories and/or electronic devices not approved and referenced by Cryopal are used.

The following list provides the product reference codes for spare parts:

<i>Description</i>	<i>Reference</i>
Cover for GT (from GT3 to GT38)	ACC-ALU-20
Curved handle	ACC-GT-102
GT2 cap	ACC-ALU-18
Plastic canister GT3/7/9 cap	ACC-GT-4
Stainless steel canisters GT3/7/9 cap	ACC-GT-2
Plastic canisters GT11/21/35 cap	ACC-GT-5
Stainless steel canisters GT11/21/35 cap	ACC-GT-1
GT14-9 cap	ACC-GT-7
GT18/14-6 cap	ACC-GT-6
GT26 cap	ACC-GT-8
GT38 cap	ACC-GT-9
Cap for GT40 (for stainless steel canister)	ACC-GT-3
Wheel without brake for standard roller base	ACC-ALU-33
Wheel with brake for standard roller base	ACC-ALU-34
Strap for GT2	ACC-ALU-19

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## 10. Disposal

### 10.1. Disposal of GT device

The disposal procedure for the GT device is as follows:

- Disinfection/decontamination of the container
- Break vacuum by piercing the interior and exterior of the double envelope
- Sort waste into categories
- Complete a **destruction certificate to send to Cryopal (After-Sales department)** including:
  - Device ID (model, reference number, batch or serial number)
  - A photo proving the container has been pierced
  - A sworn statement that the waste has been sorted and treated via the appropriate channels

### 10.2. Disposing of accessories

All waste caused by using the GT device must be disposed of through the appropriate waste treatment channels in accordance with current regulations.

## Appendix: Monitoring containers and checking their performance

This inspection protocol is based on a differential measurement of the container's weight (container + sample + nitrogen load) over a 24-hour period. It requires no special equipment besides a precision balance. You will have different thresholds depending on the model of your container - if you exceed these thresholds, we recommend you contact the manufacturer or your liquid nitrogen supplier to find out the best action to take.

- 1) Do not remove any equipment stored in your container, such as canisters or samples.
- 2) Use scales with a display that are suitable for your equipment (0-60 kg max capacity if you have *GT40* equipment).
- 3) Fill your container with liquid nitrogen up to the top (the top is considered the bottom of the epoxy neck and the cap should not be floating).
- 4) Place the full *GT* container on the scale with the cap closed (the padlock cannot be in open position).
- 5) Note the weight of the full container as displayed on the scale on a paper or electronic form, recording also the time, date, and temperature of the room.
- 6) Ensure the container remains insulated, closed, and unhandled for the next 24 hours.
- 7) After 24 hours, measure and record the weight displayed on the scale, as well as the time and room temperature.
- 8) Compare the D+24h weight with the D weight, and calculate the container loss:
  - If the loss is less than the "Warning daily evaporation" value, the container's performance is deemed acceptable.
  - If the loss is greater than the "Warning daily evaporation" value, contact your distributor to find out the best action to take.
  -

	Unit	GT2	GT3	GT9	GT11	GT21	GT35
Expected Daily	L/d	0.08	0.11	0.11	0.09	0.09	0.09
Evaporation	g/d	65	89	89	73	73	73
Warning Daily	L/d	0.24	0.33	0.33	0.27	0.27	0.27
Evaporation	g/d	194	267	267	218	218	218



	Unit	GT14	GT26	GT38	GT40
Expected Daily	L/d	0.24	0.29	0.15	0.29
Evaporation	g/d	194	234	121	134
Warning Daily	L/d	0.72	0.87	0.45	0.87
Evaporation	g/d	582	703	364	703

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