

Liquid Nitrogen for Medical Use (Medical Device). Instructions for use.



Read all of this leaflet carefully before you start using Liquid Nitrogen.

Keep this leaflet as you may need to read it again.

This leaflet gives you information about:

- What is liquid nitrogen and Indications/Intended use
- Clinical Contraindications
- Clinical side effects
- How to use liquid nitrogen for clinical application
- Safety warnings and advice for the Clinician/Healthcare establishment
- Storage and Transfer of liquid nitrogen and Associated Equipment
- Further Information

What is Liquid Nitrogen and Indications/Intended use

Liquid Nitrogen is a liquefied gas stored under pressure in purposely designed storage vessels.

Liquid Nitrogen is intended for use as a cryogen in medical applications due to the cold temperature of the liquid. The boiling point of liquid nitrogen is -196°C.

Medical Indications/Applications

Topical skin conditions (Topical Cryotherapy)

The most commonplace application for cryotherapies using liquid nitrogen is for common external skin conditions such as removal of warts, moles, verrucas, skin tags. More serious external ailments can also be addressed with this technique, such as solar keratoses and small skin cancers.

Clinical guidance for Cryotherapy should be used at all times. Clinicians using liquid nitrogen for this process should be fully trained and always follow internal procedures.

Cancers and other internal conditions (Cryosurgery using Cryoprobes)

Cryosurgery is developing rapidly as a supplement to traditional cancer therapies. Generally, all tumours that can be reached by cryoprobes are treatable (i.e. solid tumours >1 cm). However, the tiny, diffuse metastases that often coincide with cancers are not usually affected by cryotherapy.

In addition to cancerous tissues, cryotherapy has also proven a successful therapy to some soft tissue conditions such as plantar fasciitis and fibroma.

Clinical guidance for Cryosurgery should be used at all times. Clinicians using liquid nitrogen for this process should be fully trained in how to handle liquid nitrogen and always follow internal procedures.

Cryostorage

Cryostorage of biological material, (cells, tissues, blood, semen, etc.), for subsequent medical procedures and analysis.

Use with other associated devices for purpose of intended use

In order to utilise and apply the liquid nitrogen, it is intended for use with other medical devices which are designed to be compatible with liquid nitrogen both in terms of temperature and pressure, such as spray applicants (Topical Cryotherapy), probes (Cryosurgery) or freezer stores (Cryostorage).

Users should always ensure that the aforementioned Medical Devices that they purchase are compatible with liquid nitrogen and that they always follow the instructions provided by the manufacturer of these devices.



Clinical Contraindications

Topical Cryotherapy

Direct contact application of liquid nitrogen such as with a spray style applicator device is not recommended to be used on lesions where the skin is excessively damaged or broken.

Clinical Side Effects

Please be aware that a number of the points detailed in this section may also be a safety hazard for the clinician/user of the liquid nitrogen. Therefore it is important that the liquid nitrogen must always be handled by staff trained in the hazards associated with liquid nitrogen. Further information is provided in the Gases Care with Cryogenics pamphlet and Controlling the Risks of Inert Gases pamphlet which are provided when the liquid nitrogen storage installation takes place.

Topical Cryotherapy

Excessive exposure of the application site to the temperatures produced by liquid nitrogen may cause cold burns and damage/blistering to the surrounding skin. This can be temporary or permanent.

There may be temporary hypersensitisation and hypopigmentation changes when liquid nitrogen is applied direct to skin.

Cryosurgery

Side effects from Cryosurgery will depend on the specific tumour being treated – for example a treatment for skin cancer may leave noticeable scarring, swelling or burning sensations. Whereas treatment for prostate cancer may lead to perineal pain and erectile dysfunction,

although only in the short term and tumours located in the cervix may result in cramping, pain or bleeding.

General

Transient exposure to very cold gas produces discomfort in breathing and can provoke an asthma attack in susceptible people.

Low air temperatures arising from the proximity of liquefied atmospheric gases can cause hypothermia and all people at risk should wear warm clothing and minimise time of exposure to the low temperatures. However this is more likely to occur around large quantities of liquid nitrogen such as the storage tanks rather than during clinical use.

If you experience any of these side effects during use, or if you notice any other side effects not listed in this leaflet, contact BOC immediately.

How to use Liquid Nitrogen for clinical application

The liquid nitrogen is intended for use with other medical devices which are designed to be compatible with liquid nitrogen both in terms of temperature and pressure, such as spray applicants, probes or freezer stores.

Always ensure that equipment used in conjunction with liquid nitrogen is compatible with the product.

Always follow the instructions provided by the manufacturer of these applicator/freezer medical devices and storage vessels that are used in conjunction with liquid nitrogen.

Clinical guidance for Cryotherapy/Cryosurgery should be used at all times. Clinicians using liquid nitrogen for this process should be fully trained and follow internal procedures.

The liquid will vapourise on exposure to atmospheric temperatures and therefore can not be reused.

Safety Warnings and Advice for the Clinician/Healthcare establishment

Liquid Nitrogen is an extremely cold substance with a boiling point of -196°C , and should be treated with extreme caution at all times. Spills and leaks of liquid nitrogen should be avoided.

Improper handling of liquid nitrogen can be fatal and cause personal injury. To prevent this, the liquid nitrogen must always be handled by staff trained to use liquid nitrogen. Employers should ensure that procedures for the handling of liquid nitrogen are in place, and that staff have documented training in these procedures.

Safety risk assessments and COSHH assessments should be undertaken by establishments using liquid nitrogen and the associated equipment. Please review the Material Safety Data Sheet 8348, Gases Care with Cryogenics pamphlet and Controlling the Risks of Inert Gases pamphlet for further details regarding liquid nitrogen when performing these.

Adequate emergency procedures must be in place in the event of a liquid spillage, cold burn or suspected asphyxiation.

Embrittlement of materials

Contact of liquid nitrogen with some materials can cause embrittlement which will result in these materials breaking more easily and an increased risk of sharps injuries/cuts for personnel handling the broken material. Where possible these materials should not be used with liquid nitrogen.

Containers used to store biosamples at cryogenic temperature either in liquid nitrogen or the vapours of liquid nitrogen may become more brittle due the low temperatures and break more easily leading to the possibility of sharps injuries.

Other Risks

Avoid contact of liquid nitrogen with the eye by wearing a face mask.

If liquid nitrogen does enter the eye rinse eyes immediately with lukewarm water, not exceeding 37°C for at least 15 minutes and seek further medical treatment.



Storage and Transfer of Liquid Nitrogen and Associated Equipment

As well as the devices used to apply/utilise liquid nitrogen in its intended clinical use, storage vessels and dewars for the bulk storage and transport of liquid nitrogen to the place of use will be required. Again, it is important that these are compatible with liquid nitrogen and comply with all relevant standards and specifications. BOC can aid clinicians/healthcare establishments with their choice of storage/transport systems if required.

Storage of Liquid Nitrogen

When choosing a pressurised vessel system for the delivery of and storage of large quantities of liquid nitrogen (> 200 litres) make sure they are properly labelled. Always follow the instructions of the manufacturer of the pressurised vessel system. BOC can aid with the selection, implementation and maintenance of these large storage facilities if required.

Follow daily checks of the storage system as described within the manufacturer's instructions. Always ensure that the level of liquid nitrogen within the storage tank is sufficient for your needs. A lack of liquid nitrogen within the storage system may result in a delay in treatment options and damage of important samples.

Maintenance of storage equipment

Daily inspection of all liquid nitrogen storage equipment must be made by the user to detect any leaks or other malfunctions. For more information see the manufacturer's user manual. Service and maintenance of the vessels and accessories should be performed by trained and qualified personnel. Contact BOC in case of leakage and unnatural pressure change in the main storage vessel.

Transfer of Liquid Nitrogen between equipment

When transferring from the large store to smaller transport containers/dewars or clinical applicators always follow the instructions of the manufacturers of the equipment.

Use personal protective equipment and clothing as described in the Gases Care with Cryogenics pamphlet

Ensure that people transferring the liquid nitrogen are fully trained in handling liquid nitrogen and associated equipment.

Before filling is started, make sure the vessel containing the liquid nitrogen is stable and unlikely to tip. This is not applicable for the larger storage tanks that will be architecturally fixed in place.

Associated Equipment Use, Storage and Maintenance

Liquid Nitrogen can not be stored for any specified period of time in non pressurized/non insulated transport vessels, dewars or applicators as the liquid will boil to gas. All containers/aplicators used in conjunction with liquid nitrogen should be stored in a well ventilated area to ensure any residue nitrogen can escape to the atmosphere when it boils to gas. Liquid Nitrogen should not be stored in containers that are not designed to store cryogenic gases. Refer to associated equipment manufacturer's instructions.

Ice plugs can form in the neck of dewars and can be ejected at high velocity due to pressure build up. Avoid them by ensuring that protective caps are always used and that dewars are fully emptied before being taken out of use or put into storage.

Safe working procedures must be developed and adhered to for the use of dewars, including their transportation within and around the premises. Special safety procedures are necessary when carrying filled dewars in lifts. Only use dewars that are correctly and clearly labelled. Always ensure that adequate ventilation is provided in areas where dewars are filled, used or stored.

Associated equipment must be maintained in accordance with the manufacturer's instructions.

Please refer to guidelines on siting of liquid cylinders or vessels in buildings and Movement of Cryogenic vessels in lifts for further information regarding safe handling of liquid nitrogen.

Shelf Life of Liquid Nitrogen

Due to heat inleak through the storage vessel walls liquid nitrogen will boil to gas and will vent to atmosphere on a regular basis. The level of liquid nitrogen will be continuously dropping. The exact length of time that the liquid nitrogen will last between deliveries will depend on the insulation and pressure capabilities of the storage vessel and the amount of liquid nitrogen that is transferred for use into other containers/dewars/applicators. Therefore, it is important that deliveries are scheduled to ensure the amount of liquid in the storage vessel is maintained for the required usage rate of the liquid.

Further Information

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Please refer to further information relating to cryogenic gases and liquid nitrogen MSDS available from www.BOCOnline.co.uk or contact

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Notes.

Notes.

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