

Nitrospray® Plus Nitrospray® Plus Lite

Trigger Operated, Closed System, Liquid Nitrogen Cryosurgical Unit



Intended Use

To provide a means of transporting liquid nitrogen to the patient and to dispense the liquid nitrogen as a cold gas in a controlled manner during general and dermal cryosurgical procedures. The gaseous nitrogen, when dispensed is at a temperature of -196°C.

Device Description

Premier Nitrospray Plus Cryosurgical Unit constructed of a double-walled vacuum stainless steel container (canister) to hold liquid nitrogen. The outflow track extension port, located on the top of the instrument has a luer-lock connector to easily engage/disengage spray tips and other attachments as required. Included accessories are spray tips of various diameters to vary flow rate, and a tip protector. For optional accessories, refer to the Available Accessories chart.

Contraindications

- Cryosurgery is not considered to be a standard treatment for inoperable malignant melanoma.
- Patients with cold urticaria, cold intolerance, cryofibrinogenemia and cryoglobulinemia are best treated by other means.
- Cryosurgery should not be treated on tumors with indistinct borders.
- Deep-freezing is not recommended for lesions at the corners of the mouth or the vermilion border.
- Caution should be observed in dark-skinned patients for lesions that overlie nerves and for tumors located at the inner canthi, free margin of alae nasi and the auditory canal.

PRECAUTIONS

- Do not fill liquid nitrogen more than 2/3 full of container.
- Do not invert or drop a Nitrospray Unit containing liquid nitrogen.
- Proper eye protection and body wear is necessary when handling liquid nitrogen.
- Prior to first and subsequent usage, inspect the trigger assembly mechanism for any unintended obstructions.
- Spray tips should be inspected prior to each use for cracks, breaks and any other damage.
- Do not simultaneously obstruct outflow track and depress trigger, as this will interfere with proper venting and could allow excessive pressure to build within the instrument.
- Always remove and replace the cap slowly from a filled container to compensate for pressure build-up. Allow the natural agitation or bubbling to subside before securing the cap to the container.
- To prevent the unintended spray of liquid nitrogen, it is important to verify the proper luer-lock connection of accessories to the Nitrospray unit Outflow track.
- Prescription device, Rx only. For use by a licensed health professional.

WARNINGS

- Cryosurgery (liquid nitrogen spray) produces painful burning sensation on the skin, when applied.
- Do not operate Nitrospray Plus/Nitrospray Plus Lite without securely mounting the appropriate cryogenic delivery accessory for the intended procedure. Failure to do so, may result in injury to patient.
- Do not grasp or use the outflow track (spray nozzle) as a lever when capping, uncapping or tightening the unit. This may result in damage to the unit and render it inoperable.
- For external use only. Contents under pressure.

ADVERSE EVENTS

- Skin irritation, burning sensation and blistering may result if the device is not used as intended.

Materials

- 303 Stainless Steel – ASTM A582
- 304 Stainless Steel – ASTM A269
- ACETAL – ASTM D6778

Contents and Setup

| Base Unit Options |
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| 1006060 – Nitrospray Plus (16 oz. fill capacity) |
| 1006065 – Nitrospray Plus Lite (10 oz. fill capacity) |
| Included Accessories |
| 1006525 – Spray Tips, set of five (5): 16, 17, 18, 19 and 20 gauge (one each) |
| 1006527 – Spray Tip Protector |
| Available Accessories |
| 1006516 – Spray Tip, 16 gauge |
| 1006517 – Spray Tip, 17 gauge |
| 1006518 – Spray Tip, 18 gauge |
| 1006519 – Spray Tip, 19 gauge |
| 1006520 – Spray Tip, 20 gauge |
| 1006521 - Screw-hub Accessory Adapter |
| 1006525 – Spray Tips, set of five (5) |
| 1006527 – Spray Tip Protector |
| 1006530 – Bent Spray Extension |

- Depending on the varying flow rate required for treatment, select appropriate standard size spray tips provided.
- Install the desired spray tip or accessory in the luer-lock end of the outflow track. Ensure tip protector mounted securely on the spray tip.

Directions for Use

Cap Removal

- Place the vacuum container on a flat surface in a vertical position with the outflow track pointed away from you and others at all times to remove the cap.
- Place hand on the cap and remove it by turning the canister clockwise. Do not grasp or use the spray nozzle as a lever when removing the cap.
- To remove the cap when liquid nitrogen is in the canister; allow the cap to warm before attempting to remove it from the container.

Filling

- Serial numbers on the inside of cap and on the canister's label should always match.
- Fill unit to 2/3 of its capacity. This yields an average of 3-6 hours of varying intermittent usage.
- To refill the unit when liquid nitrogen is still in the canister; depress the trigger to release internal pressure and remove cap. Position the nozzle away from you and others.
- After refilling, recap securely.

Cap Tightening

- Place the vacuum container on a flat surface in a vertical position with the outflow track pointed away from you and others at all times to remove or tighten cap.
- A tight seal between cap and canister is essential for proper function. Once filled, wait for the liquid nitrogen to calm.
- Slowly turn the vacuum container counter clockwise while holding the cap stationary until you reach a firm stop. There is no need to over tighten the cap.

Operating the Nitrospray Plus/Nitrospray Plus Lite

- Depressurize container by actuating the trigger assembly mechanism before opening cap of the vacuum-sealed container.
- Ensure the container holds adequate amount of liquid nitrogen for intended cryosurgical procedure. Check cap sealing to ensure proper seating and securely tightened to the container.
- Adjust or rotate the curved trigger to provide unobstructed view of treatment site. The trigger mechanism is flexible for both left and right-handed users.
- Position the trigger mechanism such that the cap can be securely grasped, while being able to comfortably reach the trigger mechanism.
- During use, the vacuum container will become cold to touch and can become colder depending upon the length of time used. Comfortably hold the Nitrospray unit by the grooved cap.
- Depending on the varying flow rate required for treatment, select appropriate standard size spray tips.
- Install the desired spray tip or accessory in the luer-lock end of the outflow track. Ensure tip protector is mounted securely on the spray tip.
- Slowly depress the trigger mechanism and the Nitrospray unit will begin to dispense liquid nitrogen spray. The unit flow rate is disengaged by releasing the trigger mechanism.
- Device designed with self-actuating pressure-regulated valve, which delivers consistent spray and predictable freezing.
- The base holder allows Nitrospray unit to rest securely on a flat surface, when not in use.

Cleaning

- Premier Nitrospray Unit does not require cleaning or sterilization.

Storage and Handling

- Do not store with liquid nitrogen when the unit is not being used for prolonged periods of time.
- Store and handle liquid nitrogen in ventilated areas.

- Extra care should be taken while handling container filled with nitrogen,
- Avoid contact with acids, flammables or caustic solutions.
- Ambient temperatures should not exceed 27 °C (80 °F) when filled.
- Always point the outflow track away from you when handling the instrument.

Shelf Life

- Unfilled device (Container) has an indefinite shelf life.
- Device filled with liquid nitrogen has a static hold time of 6 – 8 hours.

Service

- Dents and other minor abrasions are expected through normal use. Unless the wall of the container is punctured or severely damaged, these should not present any problem.
- Premier recommends basic service for every five (5) years to keep the Nitrospray unit in safe operating and handling condition.

Warranty

Nitrospray Unit warranted for three (3) years from date of purchase against defects in workmanship or parts. Warranty is void if the unit is subjected to improper use or damage and unauthorized repairs.

To register your Nitrospray Plus and Nitrospray Plus Lite online, go to: premiermedicalco.com/medwarranty or contact Premier Customer Experience for assistance at 1-888-670-6100.

For Further Information

Please visit premiermedicalco.com.



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