

GENOSYL[®]

DELIVERY SYSTEM

The First and Only Inhaled Nitric Oxide Delivery System Approved for Interhospital Transport Across Ground, Fixed-Wing and Rotary Wing Environments

GENOSYL[®] DS has been vigorously tested across all appropriate standards per FDA and FAA requirements.

- Proven to withstand the use environments of ground, fixed-wing, and rotary wing transport.
- Static pull and EMI / EMC tested.
- Custom transport mount created with Quick Connect Plate designed to interface with common sled connections.



GENOSYL DS Key Benefits

- **Tankless, cassette-based system** eliminates the need to reconfigure transporter to accommodate cylinders
- **Compact design** provides easy access during transport
- **Helical Mounts** provide a high level of isolation from shock and vibration
- **Reduced weight**, more than 50% lighter than tank-based systems
- **Flexibility in patient transfer** allows for a simple patient handoff from the acute care setting to the transport vehicle

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INTERHOSPITAL TRANSPORT ACROSS
GROUND, FIXED-WING AND ROTARY WING ENVIRONMENTS

General Information and Indications for Use

PART DESCRIPTION	WEIGHT (per system)	DIMENSIONS (per system)	ENVIRONMENTAL RANGES		
SYSTEM TOTAL (x2) 1 Console 1 Transport Mount 1 Power Supply	11.3 kg (25 lb)	41.4 cm x 32.3 cm x 20.1 cm (16.3 in x 12.7 in x 7.9 in)	STORAGE / TRANSPORT	Temperature	-20° C to 60° C
				Humidity	15% to 95%, non-condensing
				Pressure	57 kPa to 110 kPa

- For use in interhospital patient transport, the Primary and Backup GENOSYL DS Console must be securely mounted within the transport vehicle per hospital / transport protocols.
- Prior to using the GENOSYL DS in patient transport a Cassette should be inserted into each Console.
- Transport equipment weight should be calculated to assure transport system meets weight allowance.
- **WARNING:** ONLY use the GENOSYL Delivery System with Bio-Med Crossvent 2+/2i+ with Constant Flow ON. Not doing so may lead to elevated NO₂ levels or dose variability.

For information on transport specific ventilators, please see Operator's Manual.

INDICATION & IMPORTANT SAFETY INFORMATION:

GENOSYL is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

- GENOSYL is contraindicated in the treatment of neonates dependent on right-to-left shunting of blood.
- Abrupt discontinuation of GENOSYL (nitric oxide) gas, for inhalation may lead to worsening oxygenation and increasing pulmonary artery pressure.
- Methemoglobin, NO₂, and PaO₂ should be monitored during nitric oxide administration.
- In patients with pre-existing left ventricular dysfunction, GENOSYL may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- The most common adverse reaction is hypotension.
- Nitric oxide donor compounds may have an additive effect with GENOSYL on the risk of developing methemoglobinemia.
- GENOSYL must be administered using a calibrated GENOSYL Delivery System. Only validated ventilator systems or nasal cannulas should be used in conjunction with GENOSYL.
- See package insert for additional Important Safety Information.