USE IN MRI SUITE

INNOVATION IN THE DELIVERY OF INHALED NITRIC OXIDE

GENOSYL®
DELIVERY SYSTEM

SIMPLIFIED TANKLESS SOLUTION

GENOSYL® DS is Conditionally Compatible up to the 100-Gauss Line

- Compatible with 1.5 Tesla and 3.0 Tesla diagnostic imaging environments
- Compact, portable design is free to move and store
- Gauss alerts provide redundant safety alarm sounds if the system is too close to the scanner (greater than 100 gauss)
- Sample line extension maintains system position outside the exclusion zone, allowing uninterrupted nitric oxide dosing when MR scanner is in use
- All single-use, disposable accessories are MRI compatible
- Tether attachment point allows for use of a tether when needed
- Locking casters secures Cart in place outside of the exclusion zone to prevent movement during MR scans

Using GENOSYL® DS in the MR Scanner Room

1. MRI CONDITIONAL STATUS

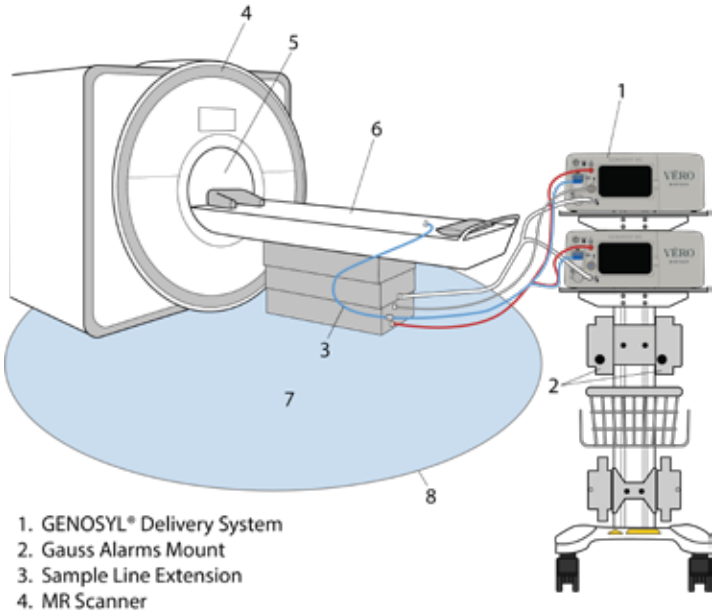
- GENOSYL DS is MR Conditional at 1.5 Tesla and 3.0 Tesla field strengths, when operated in areas where the magnetic field strength does not exceed 100 gauss.

2. GAUSS ALARM FUNCTIONALITY:

- Verify that both gauss alarms are installed on the GENOSYL DS Cart.
- Verify at least one gauss alarm is functioning properly. by testing with the VERO provided test magnet, prior to use in the MR environment.

3. POSITIONING THE SYSTEM IN THE MR SCANNER ROOM:

- Always verify that the GENOSYL DS Cart casters are locked after positioning the System in the MR scanner room
- Ensure GENOSYL DS Cart basket is clear of any extra equipment and Cassettes prior to entering the MR Scanner Room.
- A Sample Line Extension may be required (Refer to the GENOSYL DS Operator's Manual, section 3.5.2 for installation instructions)
- A facility supplied tether may be attached to the GENOSYL DS Cart handle (located at the back) as a redundant means to limit the distance the Cart moves
- Always arrange power cord, MR patient gas sample line, and NO delivery line to avoid entanglement, strangulation and/or a trip hazard



1. GENOSYL® Delivery System
2. Gauss Alarms Mount
3. Sample Line Extension
4. MR Scanner
5. MR Scanner Bore
6. Patient Table
7. Exclusion Zone (actual shape may vary)
8. 100 Gauss Line

INDICATION AND 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, NO_2, and PaO_2 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.
- NO_2, nitric dioxide; OR, operating room; PaO_2, partial pressure of oxygen.

VĒRO BIOTECH

Please refer to the full Prescribing Information and Operator's Manual.
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