Frequently Asked Questions

RhinoChill™ IntraNasal Cooling System Medical Information

How does the RhinoChill System cool the patient?

The coolant is highly volatile and has a low surface tension. When the liquid coolant is mixed with the gas propellant, it is nebulized within the nasal cavity. The low surface tension enables the nebulized liquid to spread throughout the entire volume of the nasal cavity. The nasal cavity is designed to warm inspired air to body temperature for respiration, and this mechanism evaporates the volatile liquid. Phase change of the coolant from a liquid to a gas removes 35 calories of heat per every ml of liquid coolant. Heat is removed directly from the area surround the nasal cavity via conduction. The nasal cavity is extremely well vascularized - which facilitates the warming mechanism, and therefore both the venous and arterial blood is cooled via convection. The brain is cooled preferentially by both mechanisms, and systemic cooling is achieved by convective hematagenic cooling. In the absence of circulation, the brain is cooled via direct conduction.

What is the risk class?

The RhinoChill™ IntraNasal Cooling System is classified as IIb under the European Medical Device Directive.

What are the contraindications to the use of the RhinoChill System?

Contraindications to hypothermia (Raynaud's disease, Cryoglobulinemia, Sickle Cell disease), specific temperature-sensitive pathologies (e.g., serum cold agglutinins, Buerger's disease), have bleeding disorders (e.g., hemophilia) require oxygen supplied at >50% FiO2 to maintain normal saturation (>94%), have an intranasal obstruction or known skull base fracture.

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What are the potential side effects from cooling with the RhinoChill System?

Risks associated with the use of the RhinoChill System include those related to the use of the device as well as those related to systemic hypothermia. Therefore, contraindications to cooling (e.g., cold-related pathologies or non-induced coagulopathy) should be adhered to when considering use of the RhinoChill System. Similarly, prophylaxes to common side effects of cooling should also be considered.

The RhinoChill System has been used in 213 patients in sponsored clinical studies. The most common side effects are the following:

- Discoloration of the nasal tissue ≈ 10%
- Epsitaxis ≈ 5%
- Peri-orbital emphysema ≈ 1%

Side effects were typically of short duration and resolved spontaneously.

Nasal tissue discoloration is more likely to occur in patients with poor peripheral circulation (cardiogenic shock) or no spontaneous flow (cardiac arrest).

Peri-orbital emphysema was observed in patients with a history of chronic sinusitis.

What should be done if the patient's nose turns white?

If the patient's nose turns white while cooling during ACLS, no action should be taken. If the patient achieves ROSC, the discoloration will resolve with return of peripheral circulation. Vasodilatory agents may hasten the resolution.

If the patient's nose turns white while cooling in the post-ROSC phase, then the flow rate is likely too high and the coolant is not fully evaporating within the nasal cavity. The flow rate can either be turned down, or the RhinoChill System can be turned off. After the discoloration has resolved, the flow can be resumed if it was turned off. If liquid coolant is ever seen splattering on the outside of the nose, then the flow is likely turned too high.

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Why is a protected airway necessary?

Vaporized coolant can reduce the oxygen content of inspired gas in the patient. The vapor pressure of evaporated coolant is 0.48 bar (363mmHg) at 37°C; it can therefore displace up to 48% of the available oxygen in the airway if it is aspirated. Hence, 100% oxygen delivery is reduced to 52% oxygen available for alveolar respiration. Airway protection ensures that the fraction of oxygen delivered is the fraction of oxygen available for respiration. Moreover, when the airway is protected, the coolant vapor is kept in the nasal cavity to facilitate brain cooling.

What happens if cooling with the RhinoChill™ IntraNasal Cooling System is begun prior to protecting the airway?

If 100% oxygen is used with the RhinoChill System there may be no detectable effect. However, if the patient has any compromised respiratory function (e.g., COPD or emphysema) they may undergo arterial desaturation due to less than adequate oxygen being available for respiration.

If air is used with the RhinoChill System, the available oxygen content could be as low as 11%. This concentration would be likely to cause an arterial desaturation and would require supplemental oxygen to be delivered if the airway was not protected.

What happens if the RhinoChill System Coolant is aspirated?

Supplemental oxygen should be delivered if the patient aspirates the coolant. Increasing ventilation breath rate and positive end expiratory pressure (PEEP) will facilitate the evaporation and expiration of vaporized coolant. The duration of treatment should be determined by blood gas values.

What happens if the RhinoChill System Coolant is ingested?

The RhinoChill System Coolant is completely inert and is immiscible with water. It is also 70% heavier than water and it will therefore rapidly pass through the digestive system. Loose stools may be observed.

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Is a neuromuscular blockade required for pre-hospital use?

Administration of a neuromuscular blockade in the pre-hospital setting should not be required. Patients should tolerate at least an hour of RhinoChill System cooling before anti-shivering measures are needed. If patients are conscious, then conscious sedation should be administered using either pethidine or propofol to lower the shivering threshold and minimize discomfort.