



Start the Revo**COOL**ution.

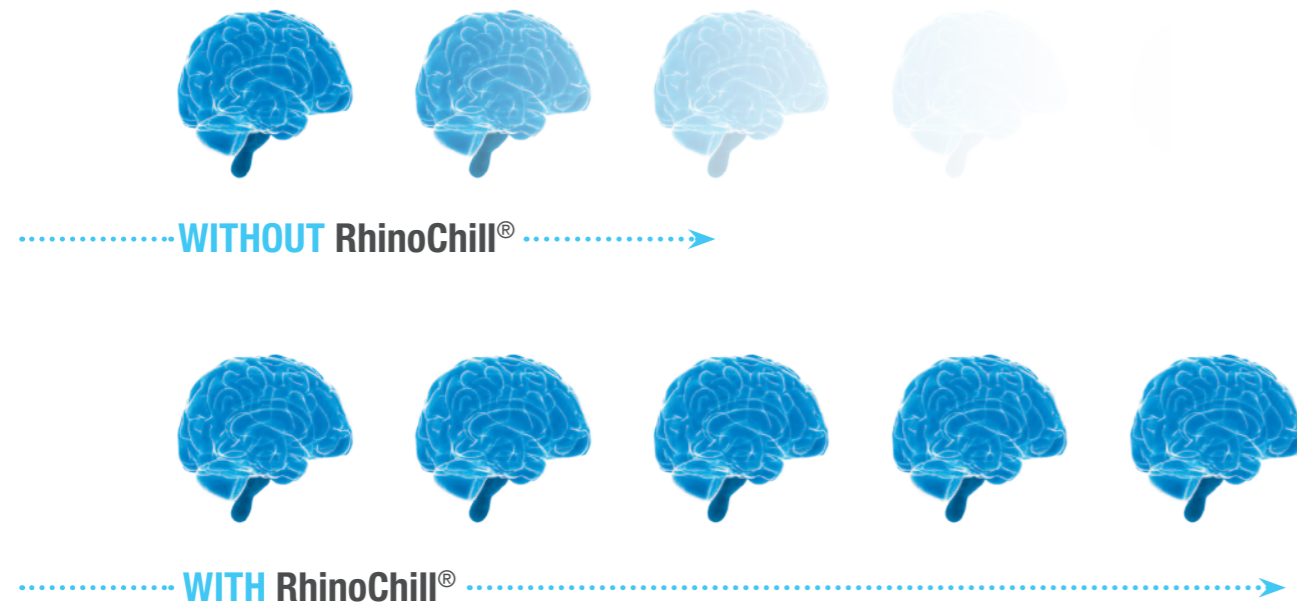


www.rhinochill.com

RhinoChill
Saving brain. Preserving life.

Start the RevoCOOLution with RhinoChill®

RhinoChill® is a practical, non-invasive solution for emergency therapeutic cooling. So when earlier, faster and easier cooling can help preserve the brains of victims of cerebral ischemic events ... start the RevoCOOLution to optimize outcomes and survival.



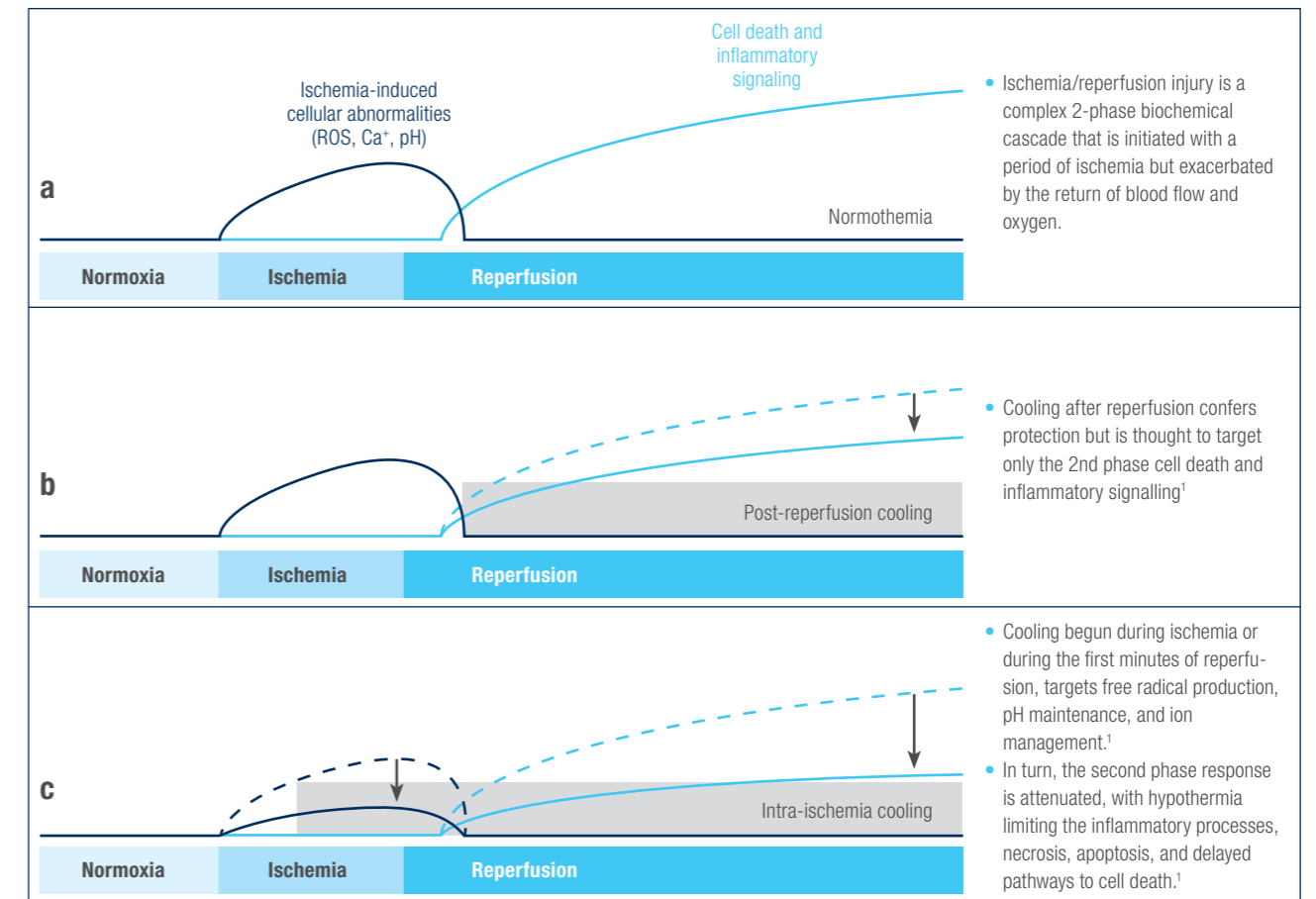
Why start the RevoCOOLution?

- Without oxygen, the brain loses 1.9 million neurons, 13.8 billion synapses and 12 km of axonal fibers – EVERY MINUTE
- Over 60% of successfully resuscitated cardiac arrest patients die due to brain damage.
 - Ultimately, starting cooling during cardiac arrest may be most beneficial because this may facilitate ROSC.*
- Stroke is the major cause of serious long time disability in adults.
 - Annually, about 16 million first-ever strokes occur in the world, the total number of stroke deaths in 48 European countries is currently estimated at 1,239,000 per year.
 - About half of the stroke survivors are left with some degree of physical or cognitive impairment.

Immediate, rapid cooling of the brain preserves cells and protects against the catastrophic reperfusion response, leading to better overall survival rates and quality of life for survivors

Why use therapeutic hypothermia in the ischemic phase?

- Therapeutic hypothermia is time critical: the mechanism of protection depends on the time between ischemia onset and hypothermia induction.¹



• Hypothermia provides multimodal protective mechanisms:¹

- reduction of cell metabolism and demand for oxygen
- maintenance of ATP
- reduction of enzymatic reaction rates
- reduction of gene expression and protein production
- improved ion management
- improved pH management

Protecting victims' brains as soon as possible greatly improves outcomes*



How does RhinoChill® work?

- RhinoChill® is the ONLY hypothermia device that uses three methods of heat transfer.
- RhinoChill® uses a transnasal evaporative catheter to deliver a mist of liquid perfluorocarbon into the nasal cavity – the perfluorocarbon evaporates on contact with the internal nares and base of skull, facilitating rapid and significant heat transfer:¹

Conductive Cooling

The thin skeletal membrane separating the brain from the nasal cavity allows efficient diffusion of thermal energy to cool the brain



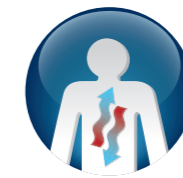
Evaporative Cooling

Nebulized coolant evaporates within the nasal cavity, initiating rapid cooling.

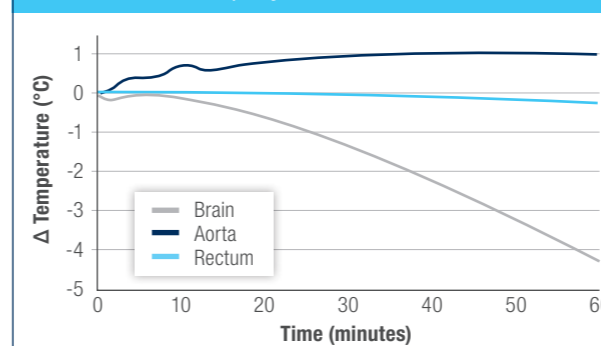


Convective Cooling

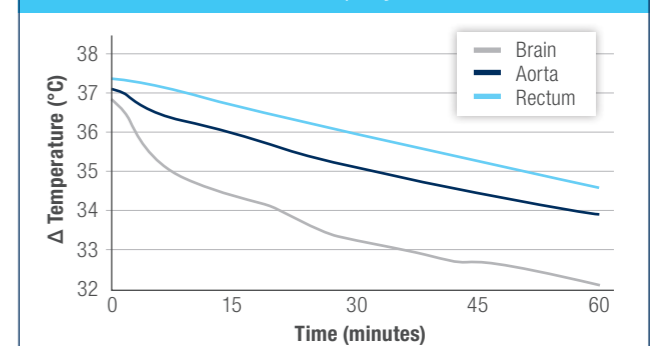
Blood flowing to the brain and returning to the heart is cooled as it passes through or near the nasopharynx. The brain and body are subsequently cooled hematogenously.



The brain cools rapidly even without circulation²



The brain and core cools rapidly with circulation^{1,2}



- While convection is dependent on blood flow, conduction is not
– **RhinoChill® overcomes the limitations of cooling methods that rely on circulation**

¹Return of spontaneous circulation.

References: **1.** Wolfson, et al. Intranasal perfluorochemical spray for preferential brain cooling in sheep. Neurocrit. Care 2008(8):437-447. **2.** Boller, et al. Feasibility of intra-arrest hypothermia induction: A novel nasopharyngeal approach achieves preferential brain cooling. Resuscitation. 2010;81(8):1025-30.

What are the benefits of RhinoChill®?

- RhinoChill® overcomes the limitations of other temperature reduction technologies – limitations that prevent early and rapid initiation of patient cooling.
- With RhinoChill®, for the first time in the history of mild therapeutic hypothermia, it is possible to effectively preserve the brain during cerebral ischemia events.¹
- Therapeutic hypothermia can be started in the field and continued until the cooled patient is connected to a maintenance cooling device in the ICU.
- RhinoChill® is easy to use, portable, compact, and its transnasal evaporative manner of cooling is recognized in the ERC guidelines as an appropriate means to induce therapeutic hypothermia.²
– "... Ultimately, starting cooling during cardiac arrest may be most beneficial." ERC guidelines 2010

RhinoChill® is a practical and portable non-invasive solution to induce therapeutic hypothermia in the field, ambulance, ER and general hospital environments

The RhinoChill® chain of survival



Early recognition and call for help



Early CPR



Early Defibrillation



RhinoChill® Cooling



Post resuscitation care



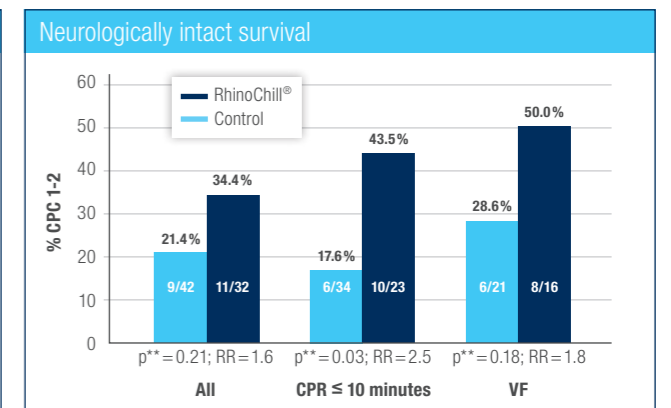
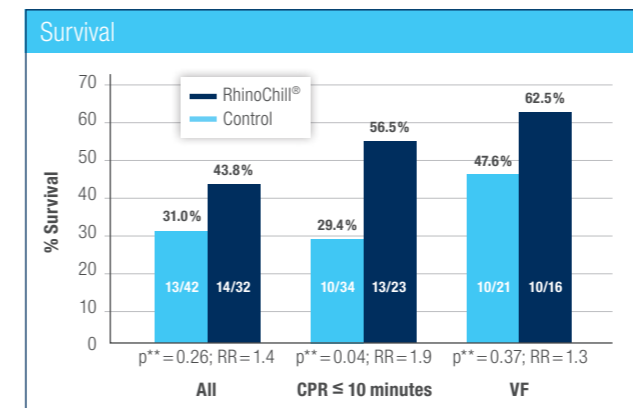
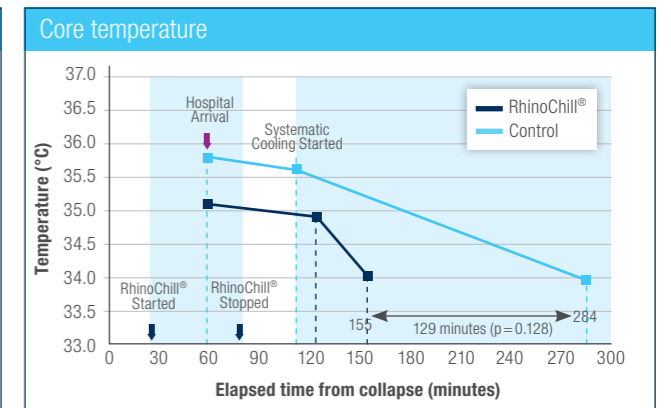
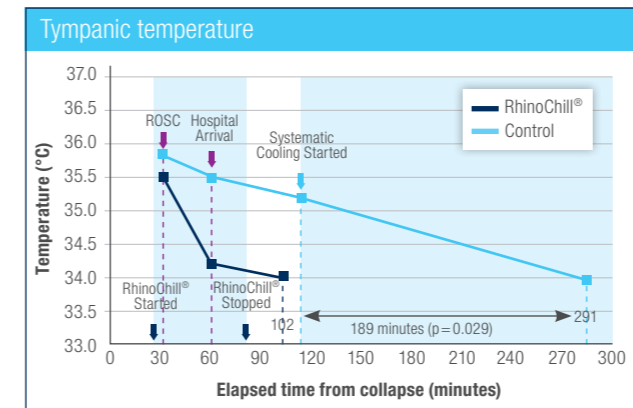


RhinoChill® – the RevoCOOLution in cardiac arrest

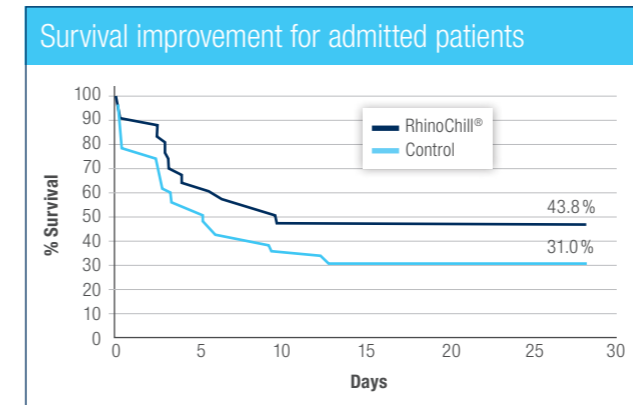
PRINCE: Pre-ROSC IntraNasal Cooling Effectiveness Study*1

PRINCE demonstrated that prehospital intra-arrest transnasal cooling with RhinoChill® is safe and feasible and provides a significant improvement in the time to cool patient's brain AND heart¹

- Intra-arrest trans-nasal cooling with RhinoChill® significantly lowers tympanic and core temperature upon arrival at hospital¹
- Time to target temperature of 34°C was shorter with RhinoChill® for both tympanic (102 vs. 291 minutes, $p=0.03$) and core (155 vs. 284 minutes, $p=0.13$) temperature.¹



- Survival to discharge and neurologically intact survival is significantly improved in witnessed arrests when CPR is initiated ≤ 10 minutes of collapse.¹



RhinoChill®: 41% relative improvement in survival for admitted patients²

- 31.0% survival with control treatment vs. 43.8% survival with RhinoChill®
- RhinoChill® may help lower overall treatment costs – In PRINCE, RhinoChill® reduced number of days spent on a respirator (4.2 vs. 8.8 days) and the number of days in the intensive care unit (8 vs. 11 days).¹

* PRINCE: Witnessed cardiac arrest patients with a treatment interval ≤ 20 minutes were randomized to intra-arrest cooling with a RhinoChill® (treatment group, n=93 final analysis) vs. standard care (control group, n=101). Both groups were cooled after hospital arrival.¹

** The study was not adequately powered to detect changes in these outcomes.

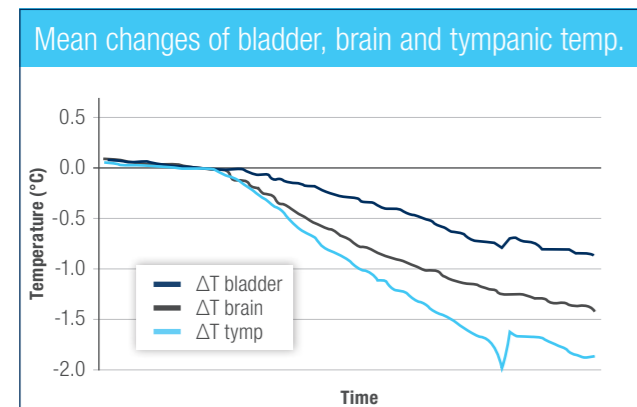
References: 1. Castrén M et al. Intra-arrest transnasal evaporative cooling: a randomized, prehospital, multicenter study (PRINCE: Pre-ROSC IntraNasal Cooling Effectiveness). Circulation. 2010;122(7):729-36. 2. Unpublished data from PRINCE.

RhinoChill® – the RevoCOOLution in stroke

- A study to assess the safety and efficacy of temperature reduction of RhinoChill® enrolled 15 patients whose brain injury was caused by intracerebral hemorrhage, trauma, and ischemic stroke in equal numbers.*
 - Hypothermia was induced for fever control in 9 patients and for neuroprotection/intracranial pressure control in 6.
 - Core temperature, brain temperature, and tympanic temperature were reduced by an average of $1.1 \pm 0.6^\circ\text{C}$
 - Intracranial pressure was reduced by an average of 32% (4.2mmHg, range: -10 – 30) in one hour.

iCool: Induction of Cooling Pilot

- A randomized trial comparing 3 methods for rapid cooling of stroke patients: Cold Infusions vs. RhinoChill® vs. Sovika®
 - iCool** was a pilot study evaluating three different induction methods in patients with ischemic or hemorrhagic stroke with regard to speed of brain cooling, feasibility and safety:²



- RhinoChill® provided selective brain cooling with temperature reductions of 1.8 °C, 1.3°C and 0.8°C in one hour for tympanic, brain, and body, respectively.

Start the RevoCOOLution

- Non-invasive
- Easy & quick to deploy
- Portable
- Effective



Specifications

| Category | Specification |
|---|--|
| Environmental Conditions | EN 1789:2007+A1:2010, Medical vehicles and their equipment – Road ambulances |
| Operating Temperature | -10°C to 50°C |
| Transport/Storage Temperature | 15° to 30°C |
| Operating Pressure | 0.8 bar to 1.0 bar (altitudes from sea-level to 2000 meters) |
| Relative Humidity | 5 % to 95 %, non-condensing |
| IP Classification (IEC 60529) | IP 34 |
| Operating Input Voltage, Control Unit | 10-18VDC, 1.5A max. |
| Operating Input Gas | Medical Grade Oxygen or Breathable Air 3.1bar to 4.8bar (45-70psi) |
| Control Unit Dimensions, Basic Assembly (H × W × D) | 39 × 26 × 16 cm |
| Control Unit Weight, Basic Assembly | 4.8 kg |



INTENDED USE

- The RhinoChill® IntraNasal Cooling System is intended for temperature reduction in patients, with a protected airway, where clinically indicated.
- The RhinoChill® IntraNasal Cooling System is intended for rapid induction of hypothermia during cardiac arrest and following resuscitation, in patients with a protected airway, in a field or hospital setting.

CONTRAINDICATIONS

Patients with known contraindications to hypothermia (Raynaud's disease, Cryoglobulinemia, Sickle Cell disease), have specific temperature-sensitive pathologies (e.g., serum cold agglutinins, Buerger's disease), have bleeding disorders, require oxygen supplied at >50% FiO₂ to maintain normal saturation (>94%), have an intranasal obstruction preventing full insertion of nasal catheters, or known base of skull fracture, should not be treated with the BeneChill RhinoChill® System.

WARNINGS

- Use the RhinoChill® Tubing Set only with the other RhinoChill® System components.
- Use the RhinoChill® Control Unit only with the other RhinoChill® System components.
- Use the RhinoChill® Coolant only with the other RhinoChill® System components.
- Use only the supplied power adaptors to recharge the RhinoChill® Control Unit.
- USE ONLY MEDICAL GRADE OXYGEN OR BREATHING AIR.
- Laser radiation – avoid direct eye contact
- The RhinoChill® System should not be used in patients without a protected airway.
- The RhinoChill® System should not be used in pregnant women.
- The RhinoChill® has not been tested in persons under 18 years of age; neither safety nor effectiveness has been proven in this population.
- Control Unit must remain in the upright position while in use.

CE 0086

EC REP

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