

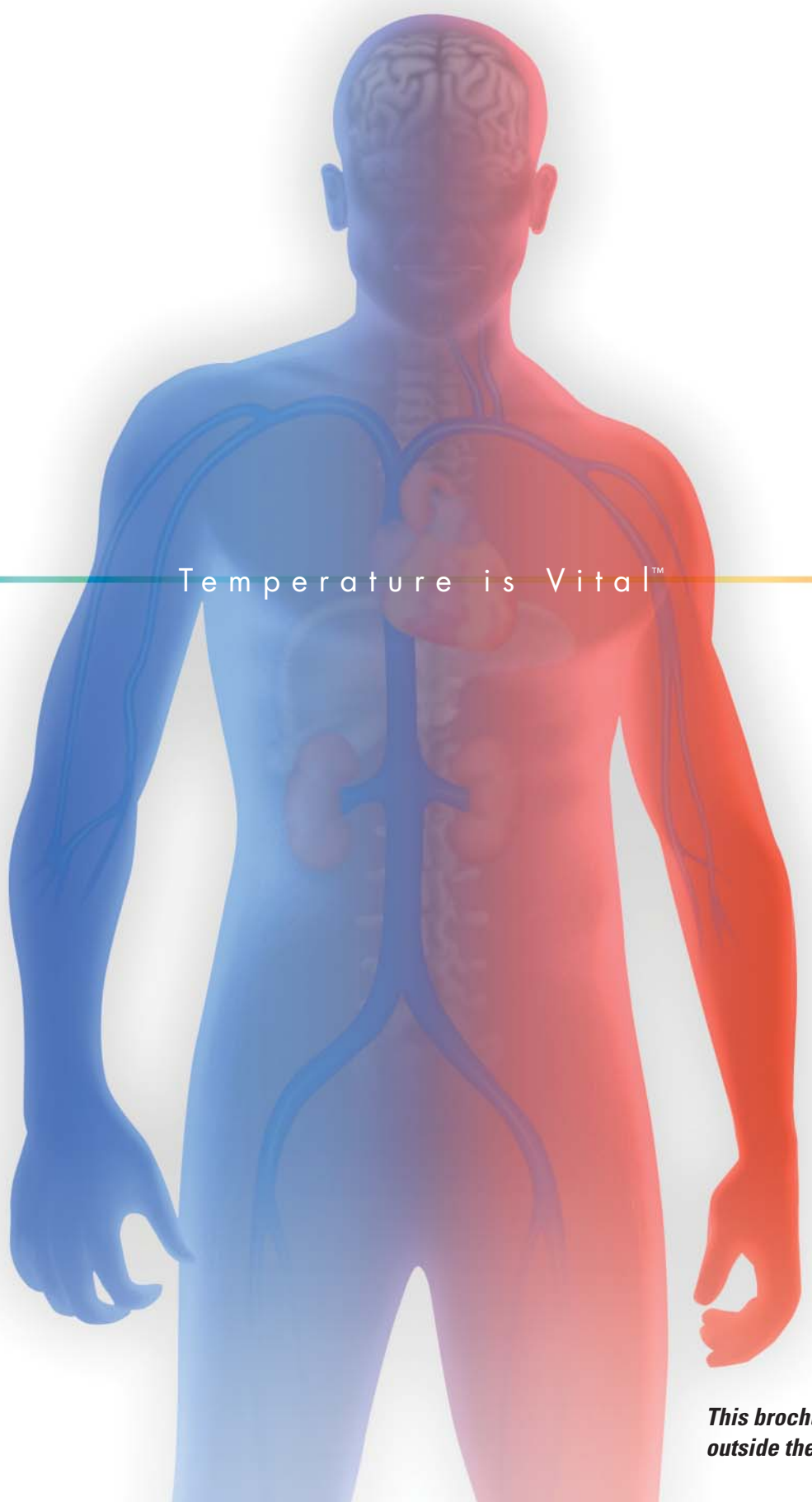
Alsius Intravascular
Temperature Management

ZOLL®

Temperature is Vital™

Cool

Warm



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Intravascular Temperature Management (IVTM)

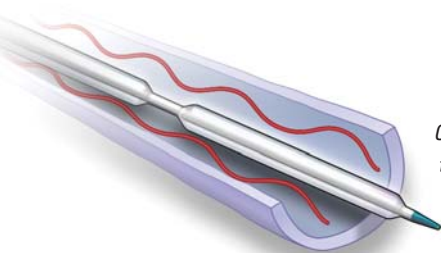
Temperature Management Is Vital to Life

Temperature is one of the four main vital signs. Management of temperature has long been recognized as vital to life. Today, major medical societies recommend temperature management as the standard-of-care treatment for many critically ill or surgical patients.

ASA	American Stroke Association
AANS	American Association of Neurological Surgeons
ESI	European Stroke Initiative
AHA	American Heart Association
ILCOR	International Liaison Committee of Resuscitation
ASA	American Society of Anesthesiologists
ASPAN	American Society of PeriAnesthesia Nurses

ZOLL's IVTM Is Vital to Temperature Management

Cooling and warming blankets, ice packs and gel pads, and other external methods are clinically inefficient, labor intensive and hinder access to critically ill patients requiring constant care. ZOLL's IVTM™ goes beneath the surface to manage core body temperature from the inside out.



Cool or warm saline is circulated through the multiple balloons of the Alsios catheter in a closed-loop design. The patient is cooled or warmed as venous blood passes over each balloon. The process is rapid and precise, offering unlimited patient access and requiring minimal nursing time.



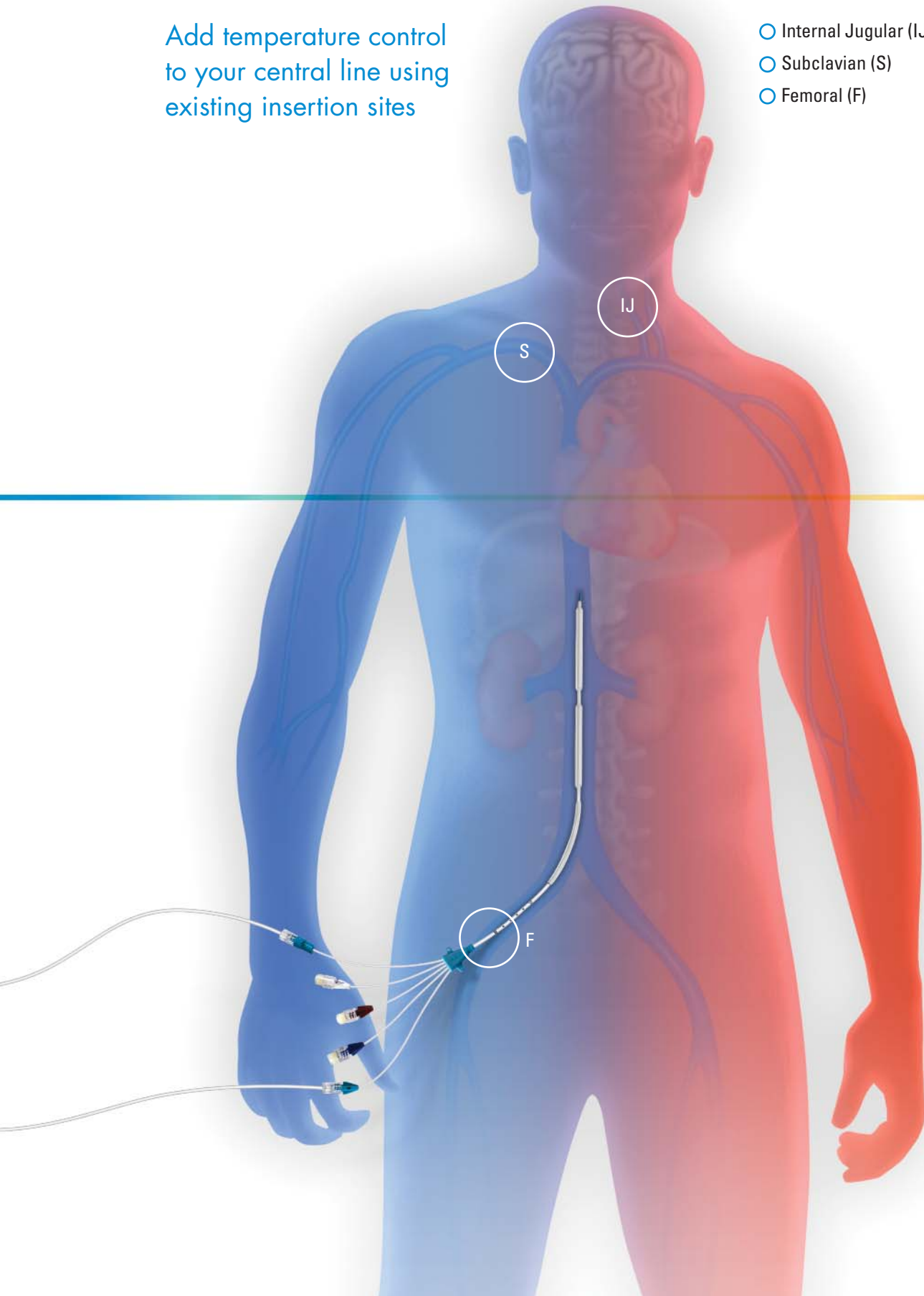
ZOLL's IVTM offers superior clinical efficiency over external methods in reaching and maintaining target temperature.^{1,2,3,4}

Cooling and Warming

From the Inside Out

Add temperature control to your central line using existing insertion sites

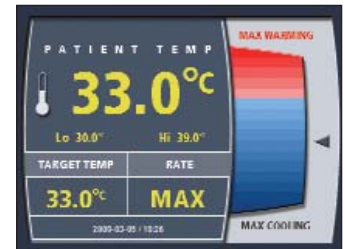
- Internal Jugular (IJ)
- Subclavian (S)
- Femoral (F)



Precise Control

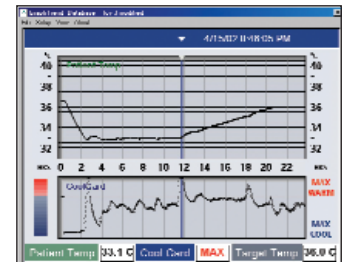
Introducing THERMOGARD *XP*

The Thermogard XP® Temperature Management System provides the next level of precise and rapid control of your patient's core temperature. The Thermogard XP provides a platform for maximum cooling and warming applications. Just set the target temperature and rate of temperature change. The Thermogard XP system adjusts the temperature of the saline flowing within the Alsius catheter balloons.



View current patient and system data on the system display or synchronize with your hospital monitor.

Patient and system data are automatically sampled every 60 seconds and a change in patient temperature as small as 0.01°C triggers an immediate adjustment in the saline temperature.



Track patient and system data and electronically transfer to the patient's file.



with **Xtra Power**

Choose the Catheter Power You Need

ZOLL offers a variety of Alsius catheter options to handle your specific patient challenges including choice of:

- **Catheter Length** - accommodate patient size
- **Insertion Site** - Internal Jugular, Subclavian, Femoral
- **Heat Exchange Power** - number of balloons

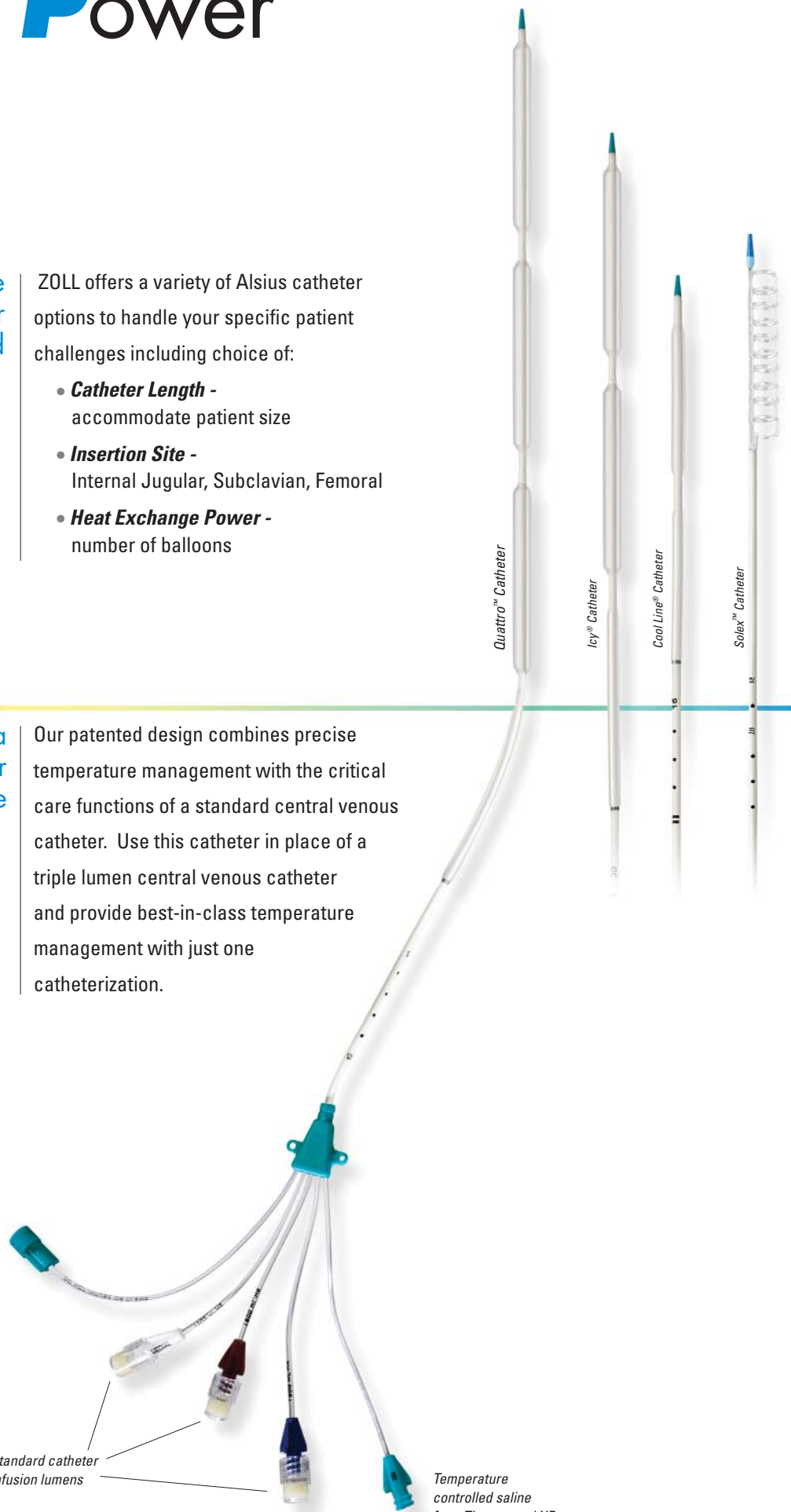
Add Xtra Power to Your Central Line

Our patented design combines precise temperature management with the critical care functions of a standard central venous catheter. Use this catheter in place of a triple lumen central venous catheter and provide best-in-class temperature management with just one catheterization.

Temperature controlled saline to Thermogard XP

Standard catheter infusion lumens

Temperature controlled saline from Thermogard XP



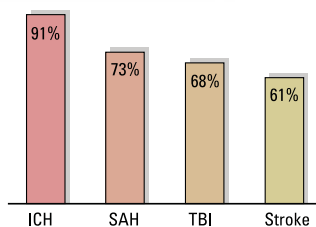
ZOLL's IVTM is Vital to

Therapeutic Cooling

Reducing Fever

Clinical studies have shown that elevated body temperature in neurologic intensive care patients is associated with a longer ICU and hospital length of stay (LOS), higher mortality rate and worse outcomes.⁵

Incidence of Fever in Neurointensive Care Unit



The Alsius IVTM system was shown to be 64% more effective than surface cooling techniques for fever reduction in neurologic intensive care unit patients.⁶

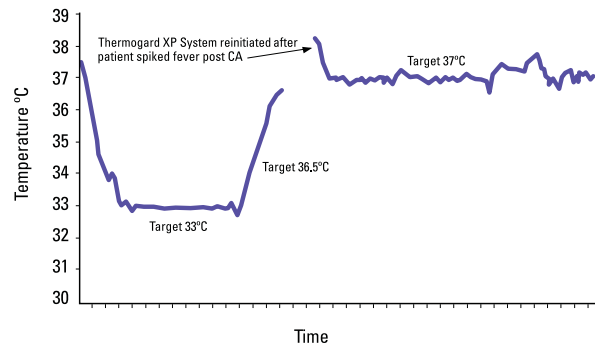
Induced Hypothermia

Both the American Heart Association and the European Resuscitation Council advocate cooling unconscious adult patients with spontaneous circulation after out-of-hospital cardiac arrest. Although this applies to patients who have experienced ventricular fibrillation (VF), cooling may also be beneficial for other rhythms or in-hospital cardiac arrest. Clinical studies have shown that induced hypothermia in patients resuscitated after cardiac arrest helps to prevent neurologic damage and improve outcomes.⁷ Caregivers understand the challenges of implementing a temperature management protocol including:

- lowering patient temperature (32°-34°C)
- maintaining target temperature for 12-24 hours
- controlled rewarming back to normal temperature (37°C)
- preventing rebound fever

ZOLL's IVTM system provides the controlled cooling and accurate re-warming required for today's hypothermia protocols.

Induced Hypothermia



Patients cooled with our IVTM system had 2-fold increased odds of survival and had significantly reduced mortality and improved favorable neurological recovery at 30 days compared with the control group.⁸

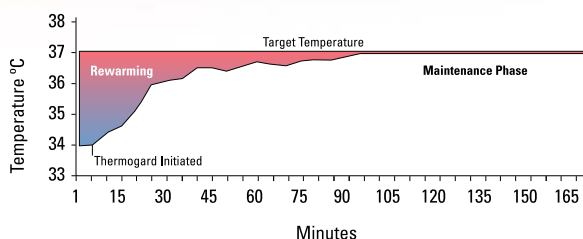
Therapeutic Warming

Perioperative hypothermia in surgical and trauma patients is associated with increased wound infection, altered drug metabolism, additional bleeding and need for transfusions, adverse cardiac events, and increased length of stay.⁹

"The Thermogard™ system is easy to use and provides effective warming during cardiac surgery."

Gary S. Allen, MD, FACS, Chief of Cardiac Surgery
Memorial Regional Hospital, Hollywood, Florida

Patient Rewarming During Cardiac Surgery

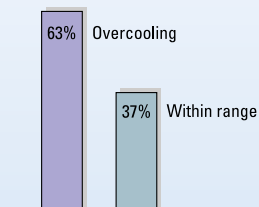


Temperature Management

External Methods Lack Control

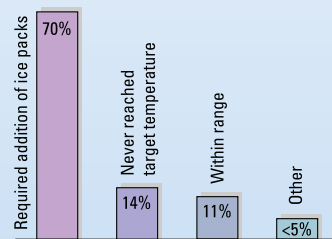
Traditional external methods lack the power and control needed to implement today's temperature management protocols.

Less Control



Nurses have a 63% chance of overcooling their patients when using surface cooling methods. This can result in serious complications, including arrhythmias, coagulopathy and increased risk of infection.⁴

Less Power



HACA Trial Using Surface Cooling

14% of patients never reached target temperatures with external cooling methods.⁷

70% of patients required the addition of ice packs.⁷

IVTM Proven Superior to External Methods

A recent study comparing the efficacy of commercially available cooling devices demonstrates the superior power and control of IVTM in reaching target temperature and keeping patients within the target range.¹

More Power

More Control

	ZOLL IVTM	Medivance Arctic Sun	Cincinnati Subzero Blanketrol II	Medeco Caircooler	Conventional
Cooling Method	Intravascular Heat Exchange	External Gel-coated Pads	External Water Circulating Pads	External Air Circulating Pads	Cold Saline, Ice Bags, etc.
Cooling Rate (°C/hr)	1.46	1.04	1.33	0.18	0.32
% Of Time Patient Was At Target Temperature (+/- 0.2° C)	96.8	55.8	49.5	25.9	30.2

Clinical Applications Where ZOLL's Intravascular Temperature Management Has Been Used

Cooling

- Fever control in Neuro/Surgical ICU
- Therapeutic hypothermia after cardiac arrest
- ICP (intracranial pressure) management
- Therapeutic hypothermia for brain trauma and stroke
- Acute liver failure
- Heat stroke
- Spinal cord injury
- Spinal surgery
- Adjunct with hemicraniectomy
- Status epilepticus

Warming

- Trauma victims
- Accidental hypothermia
- Burn surgery and intensive care
- Cardiac surgery
 - OPCAB (off-pump coronary artery bypass)
 - Post-bypass pump (prevention of after-drop)
 - LVAD (left ventricular assist device)
 - Transplant
- Thoracic aneurysm surgery
- Maintain viable donor organs for transplantation

¹ Hoedemaekers CW, et al: Comparison of cooling methods to induce and maintain normo- and hypothermia in intensive care unit patients: a prospective intervention study. *Critical Care* 2007, 11:4:R91.

² Hinz J, et al: Effectiveness of an intravascular cooling method compared with a conventional cooling technique in neurologic patients. *J Neurosurg Anesthesiol* 2007, 19:130-135.

³ Flemming K, et al: Comparison of external and intravascular cooling to induce hypothermia in patients after CPR. *GMS Ger Med Sci* 4, Dec 2006.

⁴ Merchant RM, et al: Therapeutic hypothermia after cardiac arrest: Unintentional overcooling is common using ice packs and conventional cooling blankets. *Crit Care Med* 2006, 34: S490-S494.

⁵ Diring MN, et al: Elevated body temperature independently contributes to increased length of stay in neurologic intensive care unit patients. *Crit Care Med* 2004, 32:1489-1495.

⁶ Diring MN: Treatment of fever in the neurologic intensive care unit with a catheter-based heat exchange system. *Crit Care Med* 2004, 32: 559-564.

⁷ The Hypothermia After Cardiac Arrest Study Group: Mild therapeutic hypothermia to improve the neurologic outcome after cardiac arrest. *N Engl J Med* 2002, 346:549-556.

⁸ Holzer M, et al: Efficacy and safety of endovascular cooling after cardiac arrest: Cohort study and bayesian approach. *Stroke* 2006, 37: 1792-1797.

⁹ Doufas AG: Consequences of inadvertent perioperative hypothermia. *Best Practice & Research Clinical Anaesthesiology* 2003, 17:535-549.

Alsium assets acquired by ZOLL, May 2009.

ZOLL

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