

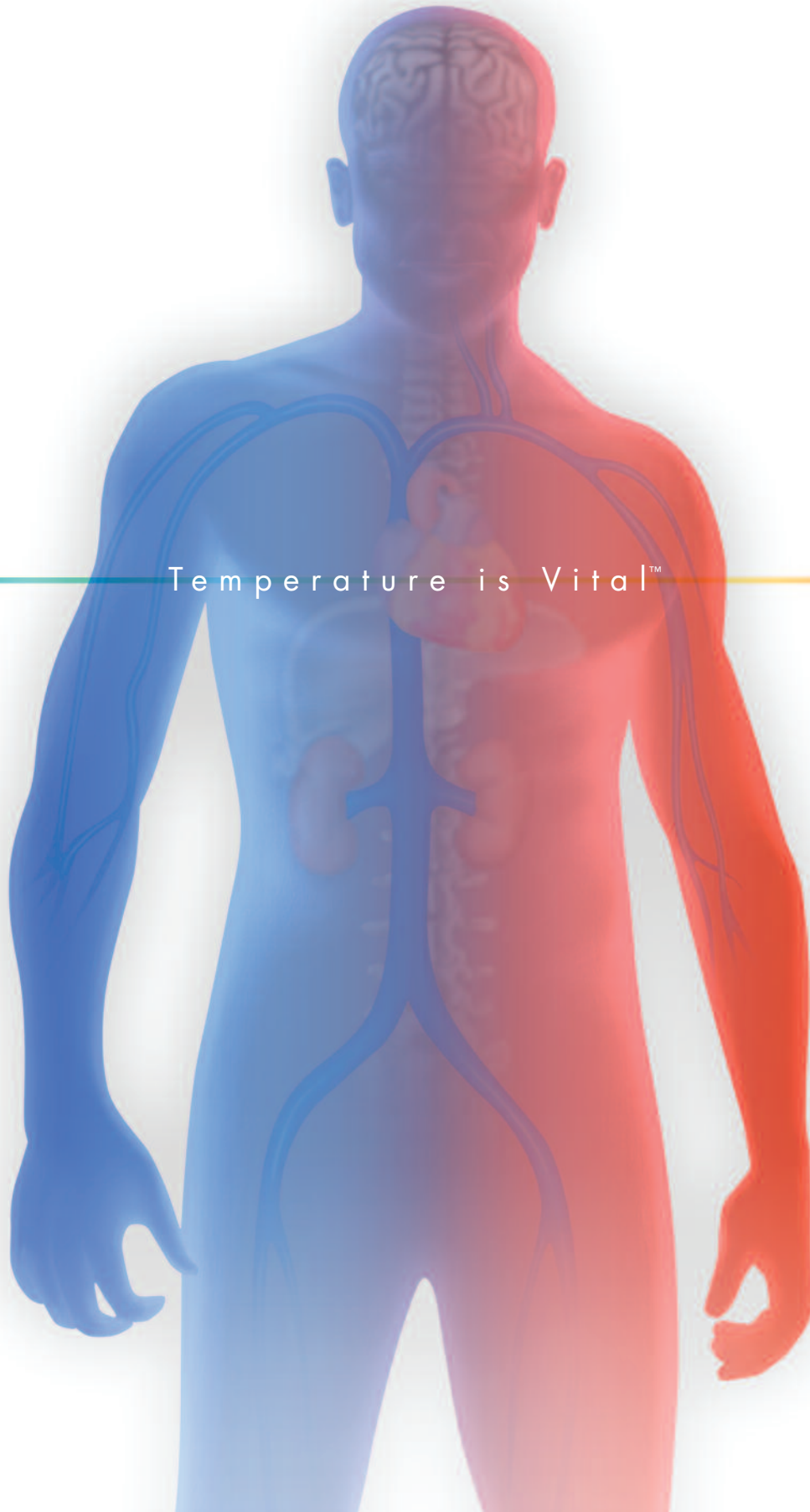
IVTM™ Intravascular Temperature
Management

ZOLL®

Temperature is Vital™

Cool

Warm



Intravascular Temperature Management (IVTM)

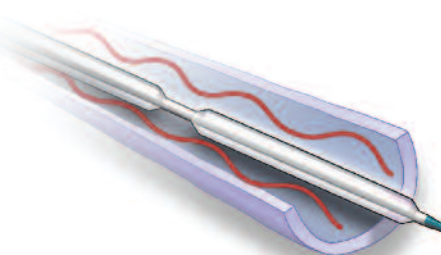
Temperature Management Is Vital to Life

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 Alsius 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}

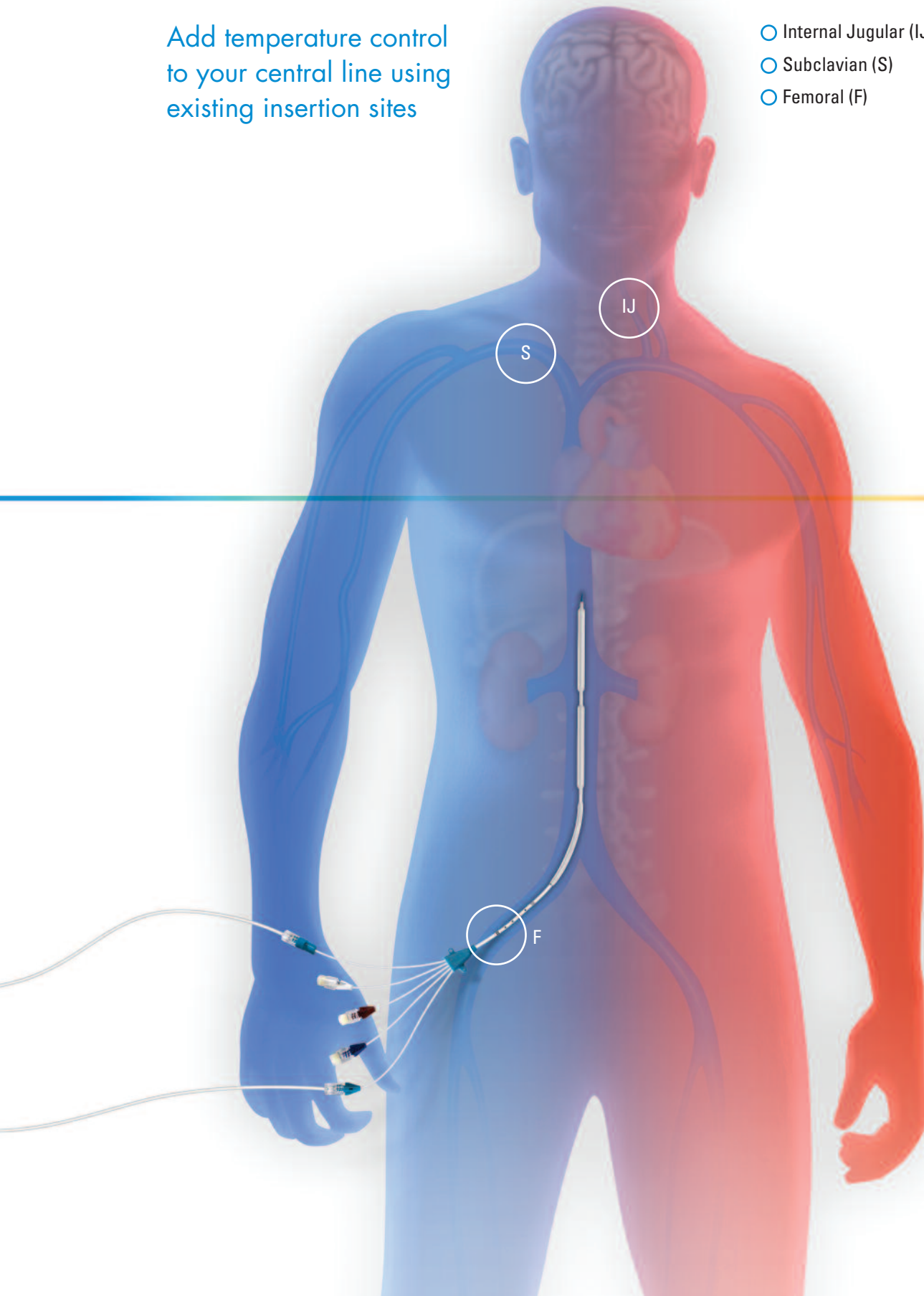


Cooling and Warming

From the Inside Out

Add temperature control
to your central line using
existing insertion sites

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

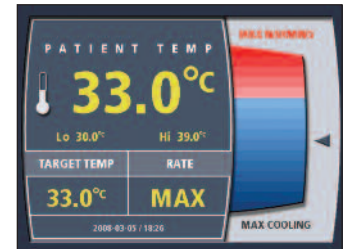


Precise Control

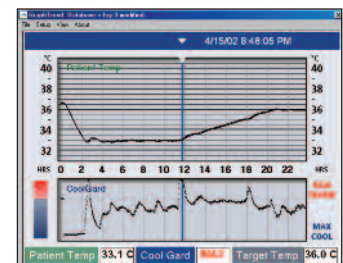
Introducing THERMOGARD^{XP}

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.

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.



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



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



with **X**tra **P**ower

Choose the Catheter Power You Need

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

- 1 **Catheter Length** - accommodate patient size
- 1 **Insertion Site** - Internal Jugular, Subclavian, Femoral
- 1 **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

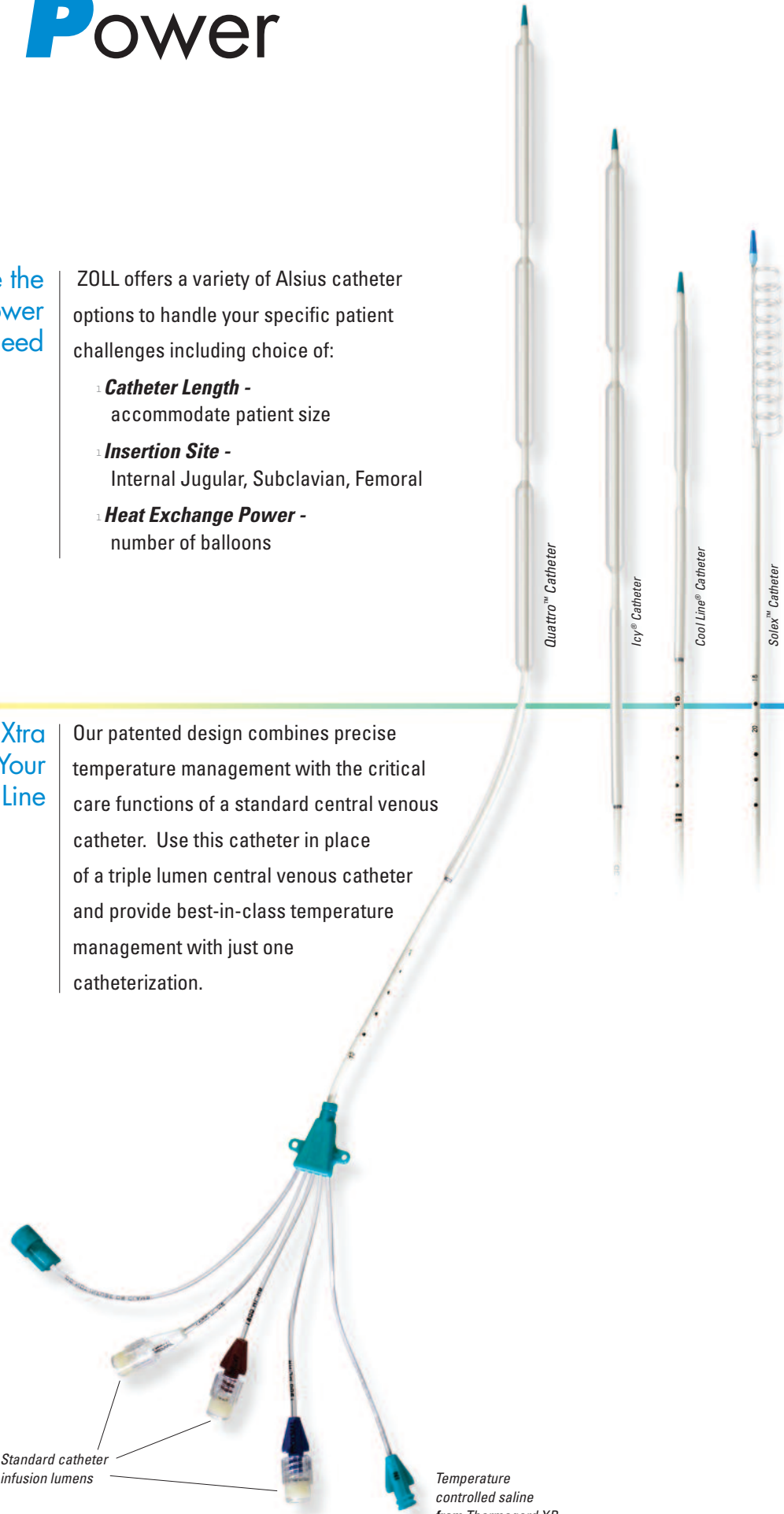
Temperature controlled saline from Thermogard XP

Quattro™ Catheter

Icy® Catheter

Cool Line® Catheter

Solex™ Catheter

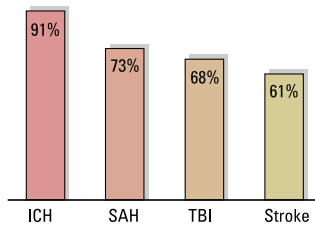


Therapeutic Cooling

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

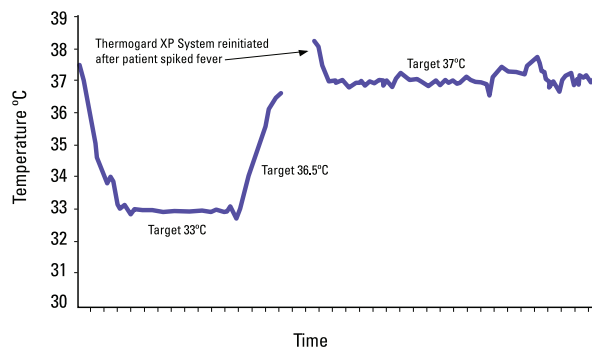
ZOLL's IVTM is Vital to

Induced Hypothermia

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

Typical Patient Temperature Rebound Fever Post Hypothermia Therapy

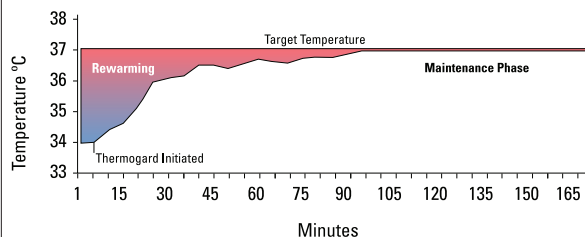


ZOLL's IVTM provides the speed and control needed for today's hypothermia protocols. Equally important to the speed and accuracy of cooling is the control of the re-warming phase of the therapy. The proprietary algorithm used in ZOLL's IVTM provides a re-warming rate as low as 0.1°C/hr and helps to control rebound fever.

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

Patient Rewarming During Cardiac Surgery



"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

Notice:

The ZOLL Intravascular Temperature Management system (IVTM) has been cleared by USFDA for the following indications only:

Icy, Solex, Quattro catheters

- In cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care.
- To induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

Cool Line catheters

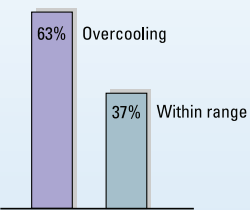
- In fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Temperature Management

External Methods Lack Control

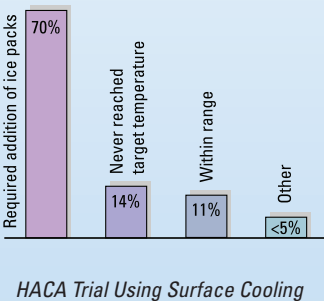
Traditional external methods lack the power and control needed to implement today's temperature management protocols.

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



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

Frequently Asked Questions About ZOLL IVTM

What's the advantage of using Intravascular Temperature Management (IVTM) versus surface cooling or warming methods?

"We participated in a randomized, controlled trial of 296 patients that showed a 64% reduction in fever using Alsius IVTM compared with best available surface methods.¹ Because we are able to directly affect the patient's core temperature using the Alsius IVTM method, via cooling and warming the venous system, we are able to more rapidly control the patient's core body temperature with greater efficiency and precision than surface methods."

Carmelo Graffagnino MD, FRCPC
Associate Professor of Medicine/Neurology
Director, Duke Neurosciences Critical Care Unit
Duke University Medical Center, Durham, NC

Isn't the IVTM method more invasive for the patient?

"No. Most critically ill patients who are candidates for temperature management already require central venous access. The fact that the Alsius catheter provides reliable temperature management and functions like a triple lumen central venous catheter allows cooling and necessary vascular access in one step."

Brent Myers, MD, MPH
Medical Director, Wake County EMS
Medical Director, Emergency Services Institute, WakeMed Health and Hospitals, Raleigh, NC

Paul Hinchey, MD, MBA
Medical Director, Mobile Critical Care, WakeMed Health and Hospitals
Assistant Medical Director, Wake County EMS, Raleigh, NC

How will using the IVTM System impact our nursing staff?

"Surface cooling is slow, uncomfortable, limits patient access, and is labor intensive for our nursing staff, often requiring intubation and paralysis to control shivering. The nurses report that using the Alsius IVTM System requires significantly less nursing time than external methods to reach and maintain target temperatures."

Rhonda Anderson, RN, MSN, CCRN, Clinical Project Manager
WellStar Health System, Marietta, GA

"I was completely sold on the idea of hypothermia induction. However, after just two patients and fighting with the external cooling blankets, we were all ready to stop the protocol." "Since we have switched to the Alsius System we have been able to shift our focus from caring for the equipment to caring for the patient. It has made life so much easier."

Kim Henson, RN
Adam Stocks, RN, BSN, CCRN, Clinical Unit Educator, CCU
Spartanburg Regional Medical Center, Spartanburg, SC

The above represents the opinions of the clinicians noted.

¹ Hoedemaekers CVW, 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 Fleming 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 Doufas AG: Consequences of inadvertent perioperative hypothermia. *Best Practice & Research Clinical Anaesthesiology* 2003, 17:535-549.

Alsius assets acquired by ZOLL May 2009.



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Specifications subject to change without notice.